Supreme Court, U.S.
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In The OFFICE OF THE CLERK

Supreme Court of the United States

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EDMUND CHEIN, M.D.,

Petitioner,

v.

MICHELLE M. LEONHART, IN HER OFFICIAL CAPACITY AS DEPUTY ADMINISTRATOR OF THE U.S. DRUG ENFORCEMENT ADMINISTRATION; THE U.S. DRUG ENFORCEMENT ADMINISTRATION; THE U.S. DEPARTMENT OF JUSTICE; AND THE UNITED STATES OF AMERICA,

Respondents.

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**On Petition For A Writ Of Certiorari
To The United States Court Of Appeals
For The District Of Columbia Circuit**

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PETITION FOR A WRIT OF CERTIORARI

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QUESTIONS PRESENTED

(1) Whether the U.S. Court of Appeals for the D.C. Circuit ("D.C. Circuit") created new law in conflict with precedent in that circuit, in its sister circuits, and in this Court by substituting its own rationale *post hoc* for that of the Drug Enforcement Administration ("DEA") Deputy Administrator ("DA"), creating three new grounds for decision not mentioned in the DA's Final Order as bases for that order.

(2) Whether, under 21 U.S.C. § 822, a physician requires an export permit (in addition to a dispense permit) to ship non-narcotic schedule III controlled substances to his own patients residing outside the United States and whether DEA's history of permitting physician exports without an export permit combined with its failure to define physician export criteria violates the Fifth Amendment void for vagueness standard and the Administrative Procedure Act ("APA") arbitrary and capricious and abuse of discretion standards.

(3) Whether the D.C. Circuit's decision to uphold the DEA DA's resort to the draconian sanction of revocation of a physician's DEA registration, when she routinely favors conditional renewals in the first instance and in comparable circumstances, creates chaos among physician regulatees such that the regulated class lacks sufficient information to discern any meaningful distinguishing principle between the standards for revocation and for conditional renewal.

QUESTIONS PRESENTED – Continued

(4) Whether the D.C. Circuit reversed its own precedent and acted contrary to this Court's decision in *Universal Camera Corp. v. NLRB*, 340 U.S. 474 (1951) when it failed to mention, let alone consider, all elements favoring the regulatee under the multi-factor public interest test prescribed in 21 U.S.C. § 823 (a)-(f).

PARTIES TO THE PROCEEDING

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The Court of Appeals for the D.C. Circuit issued its decision on July 22, 2008. That decision is reported at *Chein v. Drug Enforcement Administration, et al.,* 533 F.3d 828 (D.C. Cir. 2008) (App. 1). The Court of Appeals for the D.C. Circuit's unpublished order denying rehearing (App. 214) issued on September 19, 2008. The DEA Deputy Administrator's Final Order revoking Dr. Chein's DEA registration issued on February 12, 2007 and is reported at *Edmund Chein, M.D.; Revocation of Practitioner's Registration, Denial of Application for Exporter's Registration*, 72 Fed. Reg. 6580 (February 12, 2007) (App. 23). Administrative Law Judge Gail A. Randall ("ALJ") issued her recommended ruling on July 28, 2005. *See In re Edmund Chein, M.D.*, DEA Dkt. No. 02-9, 02-43, Recommended Findings of Fact, Conclusions of Law, and Decision of the Administrative Law Judge (July 28, 2005) (App. 105).

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JURISDICTION

The Court of Appeals entered its decision on July 22, 2008, and the Court voted to deny Dr. Chein's timely Petition for Rehearing and Suggestion for Rehearing En Banc on September 19, 2008. The jurisdiction of this Court is invoked under 28 U.S.C. § 1254(1).

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STATUTORY PROVISIONS

The constitutional provisions, statutes and regulations involved in the case are presented verbatim in the statutory addendum per Sup. Ct. R. 14(f), (i)(v).

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STATEMENT

A. Edmund Chein, M.D.

Dr. Edmund Chein is the owner of the Palm Springs Life Extension Institute in Palm Springs, California. He is a physician. He also holds a law degree but does not practice law. He maintains a license to practice medicine in California and Utah and was, before issuance of the DEA Deputy Administrator's (DA's) Final Order, registered with the DEA to dispense controlled substances (Schedules II through V). Chein is one of the world's leading experts in the field of anti-aging medicine, having pioneered and patented "total hormone replacement therapy" ("THRT"). THRT involves incremental administration of hormones in low doses to restore gradually an aging patient's hormone levels to those approximating the levels of a healthy adult. Blood levels of hormones are closely monitored to ensure proper dosing and to avoid risks to patient health.

Medical practice is becoming international and physicians who have practice specialties in the United States are in high demand worldwide. Patients from other nations routinely visit the United States for treatment, and U.S. physicians regularly travel abroad to provide medical care. Many U.S. physicians are consulted by physicians from other nations who wish to duplicate the approaches used by our leading medical experts. Prescription practice is thus becoming global. *See, e.g.*, American Osteopathic Association, *D.O.s Go Global: Osteopathic Medicine Finding a Home Outside the U.S*, (stating that American Doctors of Osteopathic Medicine have full practice rights in 44 countries and partial rights in 8 others)[1]; Amy J. Oliver, *Internet Pharmacies: Regulation of a Growing Industry*, 28 J.L. Med. & Ethics 98 (2000) (depicting increased demand for internet and cross-border medicine); David B. Brushwood, R.Ph., J.D., *Responsive Regulation of Internet Pharmacy Practice*, 10 Annals Health L. 75, 88 (2001) (discussing dangers of over-regulation of global internet pharmacies). As an internationally renowned expert in the field of anti-aging medicine, Chein instructs practitioners worldwide, and is in high demand around the world for his unique brand of treatment. He treats patients, resident in many foreign countries, together with their regular physicians and instructs doctors abroad in the proper administration of THRT.

This case involves a question vital to physicians in international medical practice. It concerns whether domestic physicians are entitled to a coherent, uniformly applied regulatory standard for dispensing non-narcotic Schedule III controlled substances as part of their medical practice to their patients resident abroad or whether they, like domestic drug makers, must obtain export permits to do so. This case also involves a question vital to physicians in the United States concerning whether the DEA DA must, at minimum, declare for physician regulatees a clear basis for distinguishing between instances in which she grants conditional renewals of registrations and instances in which she revokes registrations.

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[1] *Available at*, http://www.osteopathic.org/index.cfm?PageID =ost_dogoblobal (last visited October 27, 2008).

B. The DEA

The DEA began investigating Dr. Chein in 1994. The DEA issued two Orders to Show Cause ("OSC"), the first on November 7, 2001, and the second on May 24, 2002. The first OSC revoked Chein's registration to dispense controlled substances, while the second denied Chein's application for an exportation registration. DEA argued that Chein's continued dispensing without an export registration was inconsistent with the public interest. Following DEA administrative hearings in 2003 and July 28, 2005, the DEA Administrative Law Judge (ALJ) concluded that Chein's continued registration was against the public interest. The ALJ further recommended that DEA deny Chein's export application.

The DA issued her Final Order on February 12, 2007, an extraordinary 13 years after the DEA began its investigation of Chein. She therein revoked

Chein's registration in the first instance without analyzing it consistent with past DEA cases wherein she granted conditional registrations in the first instance on a record of comparable or more egregious facts. Moreover, the DA failed to explain why she deviated from DEA's long historic practice of condoning physician failures to seek DEA approval before dispensing abroad and of, thereafter, permitting physician dispensing to overseas patients without grant of an export application. Under 21 U.S.C. § 877, Chein timely appealed the DEA Final Order to the United States Court of Appeals for the District of Columbia Circuit.

C. The D.C. Circuit Decision and Issues Presented

Chein raised nine issues on appeal, but the D.C. Circuit addressed only the first. It ruled that the DA did not run afoul of the Administrative Procedure Act when she revoked Chein's registration (despite the fact that she had repeatedly granted continued registrations in other analogous physician registration cases). Chein relied on *Morall v. DEA*, 412 F.3d 165 (D.C. Cir. 2005), where the D.C. Circuit held that DEA's failure to explain its departure from analogous precedent rendered the revocation of a physician's registration unlawful under the APA. *See id.* at 167, 181. Although the D.C. Circuit did not identify any DA decision, policy, or rule explaining an intelligible principle that would distinguish when conditional registrations would be preferred over revocations, it nonetheless invented that principle anew and substituted it for the rationale the DA articulated in her decision. The D.C. Circuit surmised that in prior cases the DA, under the public interest standard, imposed a conditional renewal only when three factors were present. *Id.* Those factors it defined as: (1) when the physician ceased alleged law violations after notice of them; (2) when the physician accepted responsibility for the alleged law violations; and (3) when the physician cooperated with DEA. That rationale and those factors do not appear as DEA grounds for conditional renewal in the administrative Final Order, or in any other DEA decision, policy, or rule. The D.C. Circuit's opinion concluded without considering the remaining statutory factors and failed to provide Chein meaningful judicial review guaranteed by the CSA, 21 U.S.C. § 823(a)-(f) and the APA, 5 U.S.C. § 702. The D.C. Circuit's decision conflicts with precedent in this Court, sister circuits, and the D.C. Circuit by inventing for DEA *post hoc* a rationalization for decision entirely absent from the DA's Final Order.

Moreover, the D.C. Circuit decision did not address the DA's failure to explain a principled basis for distinguishing when she will grant conditional renewals of physicians' DEA registrations from those instances when she will revoke registrations outright. Without that essential distinction, physician regulatees are left at the arbitrary whim of the DEA DA who may without cogent explanation revoke a registration in the first instance in one case but on comparable facts grant a conditioned renewal in another.

The DA thus abuses her discretion and acts arbitrarily and capriciously. The regulated class of physicians cannot perform their professional duties in confidence without certain knowledge of the circumstances in which the DA will choose conditional renewal over revocation of a DEA registration. That is her irreducible burden under the APA and the Fifth Amendment void for vagueness doctrine when determining whether to revoke a physician's property interest in his or her DEA registration. 5 U.S.C. § 706; *Grayned v. City of Rockford*, 408 U.S. 104, 108-09 (1972). A statute is said to be void for vagueness if it fails to give a person of ordinary intelligence a reasonable opportunity to know what actions are prohibited. *Id.*

It had been DEA practice not to require physician registrants dispensing to patients abroad to obtain an export permit. Rather, DEA required those permits for manufacturers of schedule listed chemicals who exported those chemicals for sale). Arbitrarily, and in conflict with the CSA provisions on point, 21 U.S.C. §§ 822, 953(e), DEA compelled Chein to file an export application twice and then used his honest effort to comply as a further justification for revoking his license. The unexplained departure from DEA precedent was not addressed by the D.C. Circuit yet also invites chaos among regulatees because physicians who practice internationally must now proceed without clear standards concerning the legality of dispensing listed drugs to their patients abroad.

Because the language granting Chein his registration to dispense indicated that compliance with the specific subpart was sufficient, the general import and export statute could not reasonably be read to impose additional conditions. 21 U.S.C. § 953(e) exempts Chein from registration, requiring only that he file information with the DEA. Congress forbade DEA from regulating the practice of medicine. *United States v. Moore*, 423 U.S. 122, 143 (1975) (explaining Congress' concern that the drug laws not interfere with physicians treating patients); *see also Whether Physician-Assisted Suicide Serves a "Legitimate Medical Purpose" Under the Drug Enforcement Administration's Regulations Implementing the Controlled Substances Act*, 17 Issues L. & Med. 269, 272 (2002) (explaining intent of Controlled Substances Act was to allow physicians to dispense controlled substances only for legitimate medical purposes). Chein's interpretation of the dispensing regulation was thus reasonable. He reasonably believed that his registration to dispense to patients was necessary and sufficient to dispense to those patients even when resident overseas. Moreover, the DEA's required method to provide notice of an export, Form 236, is inappropriate in Chein's circumstance because on its face it is clearly intended for large exporters shipping listed chemicals for commercial sale abroad.

The D.C. Circuit also failed to perform the review required of it by statute, 5 U.S.C. § 702, i.e., to review all favorable evidence supporting Chein's continued registration *de novo*, a consideration required by statute and circuit precedent. 21 U.S.C. § 823 (a)-(f); *Universal Camera Corp. v. NLRB*, 340 U.S. 474, 488 (1951); *International Chem. Workers Union, Local 540 v. NLRB*, 790 F.2d 964 (D.C. Cir. 1986) (explaining that court must consider body of evidence in favor of regulatee when reviewing agency action). The DA has discretion to weigh any one or all statutory factors in 21 U.S.C. § 823(a)-(f) and she may consider one factor above others, but she must evaluate all evidence contrary to her position and favorable to the registrant. The D.C. Circuit must assess whether the DA properly considered information favorable to the registrant before imposing a Section 823 sanction. 21 U.S.C. § 823 (a)-(f); *Universal Camera Corp. v. NLRB*, 340 U.S. 474, 488 (1951) (court needs to take into account contradictory evidence or evidence from which conflicting inferences could be drawn); *see Dickinson v. Zurko*, 527 U.S. 150, 155 (1999) ("[t]he APA requires meaningful review; and its enactment meant stricter judicial review of agency factfinding than Congress believed some courts had previously conducted"). The D.C. Circuit failed to perform the required review and departed from this Court's holding in *Universal Camera*.

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REASONS FOR GRANTING THE PETITION

A. The D.C. Circuit's Substitution of Its Own *Post Hoc* Rationale For the DA's Decision Violates the Precedent of this Court, the D.C. Circuit, and the Sister Circuits

The D.C. Circuit fashioned its own independent rationale to justify the DA's revocation of Chein's registration. The Supreme Court, the Court of Appeals for the D.C. Circuit, and the sister circuits have consistently rejected *post hoc* rationalizations for agency action.[2] When the court creates justifications for agency action as a substitute for the agency's rationale, it transgresses the line between judicial review and executive action, involving the court in the business of agency policy and rule creation. The separation of powers is a core principle violated by the D.C. Circuit's creation of a *post hoc* rationale in the *Chein* case. *See Burlington Truck Lines v. United States*, 371 U.S. 156, 168 (1962); *Martin v. Occupational Safety and Health Review Comm'n*, 499 U.S. 144, 157 (1991); *see also AT&T Corp. v. FCC*, 220 F.3d 607, 631 (D.C. Cir. 2000) (decision on how to promote competition in local and long distance telephone markets was a policy judgment, therefore "it is for the agency – not this court – to make"); *Nat'l Treasury Emples. Union v. Chertoff*, 452 F.3d 839, 867 (D.C. Cir. 2006) (*quoting Harmon v. Thornburgh*, 878 F.2d 484, 494 (D.C. Cir. 1989). The Court was "obliged to respect 'the fundamental principle that agency policy is to be made, in the first instance, by the agency itself – not by courts, and not by agency counsel'"); *OSG Bulk Ships v. United States*, 921 F. Supp. 812, 825 (D.D.C. 1996) ("Chevron deference is premised on Congress's explicit or implicit delegation of interpretative authority to an agency because the agency is in a better position than a court to make policy decisions in the face of statutory ambiguity").

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[2] *See, e.g., Federal Power Commission v. Texaco Inc.*, 417 U.S. 380, 397 (1974); *Wedgewood Village Pharmacy v. DEA*, 50 F.3d 541, 550 n.13 (D.C. Cir. 2007); *U.S. v. Garner*, 767 F.2d 104, 116-17 (5th Cir. 1985); *UHFC Co. v. U.S.*, 916 F.2d 689, 699 (Fed. Cir. 1990); *Gifford Pinchot Task Force v. U.S. Fish and Wildlife Service*, 378 F.3d 1059, 1071 n.7 (9th Cir. 2004); *Marshall v. Lansing*, 839 F.2d 933, 943-44 (3d Cir. 1988).

The DA's decision must stand or fall on its own merit, without the substitution of a new rationale by the reviewing court to excuse the decision's infirmities in the DA's reasoning. *See Clark County, Nev. v. FAA*, 522 F.3d 437, 441 (D.C. Cir. 2008) ("a court is not to substitute its judgment for that of the agency"); *see also Federal Power Commission v. Texaco, Inc.*, 417 U.S. 380, 397 (1974) (court cannot accept *post hoc* rationalizations of appellate counsel).

The DA never articulated the three factors that the D.C. Circuit made central to its affirmation of her Final Order. *Compare* Final Order at 6593 (concluding evidence of Chein's non-compliance with applicable laws as inconsistent with the public interest) *with Chein*, 533 F.3d at 836 (relying on Chein's lack of cooperation, of acceptance of responsibility and of failure to heed compliance demands as basis for affirming Final Order). Nowhere in the DA's Final Order does she state that Chein's alleged failure to "correct prohibited practices," alleged failure to "accept responsibility for his conduct," or alleged failure to "cooperate with DEA" distinguished his circumstance from that in like DEA cases where she granted renewals conditioned on compliance. *Compare* Final Order at 6590-92, 6594, *with Paul W. Saxton; Continuation of Registration,* 64 Fed. Reg. 25073, 25078-79 (May 10, 1999) (registrant prescribed medication in a manner that placed his patients at risk; liberally prescribed anabolic steroids and controlled substances without a legitimate medical purpose; and provided patients prescriptions knowing they abused the medication); *Donald P. Tecca, M.D.; Continuation of Registration With Restrictions*, 62 Fed. Reg. 12842 (Mar. 18, 1997) (registrant prescribed controlled substances to undercover officers for no legitimate reason on eight separate occasions; registrant dispensed 1,640 dosages of codeine to one patient within a three month period). The D.C. Circuit's substitution of its own rationale for that of the DA is a dangerous precedent that this Court should reverse to prevent like appellate decisions from eroding the separation of powers and condoning APA violations.

Moreover, the three factors the D.C. Circuit offered to justify the DA's decision were insufficient grounds to justify revocation under 21 U.S.C. 823(a)-(f) and applicable precedent. In past cases, the DA had granted a renewal with conditions rather than revoke even when one or more of the D.C. Circuit's presumed distinguishing factors were present.[3] In a subset of those cases with comparable facts to Chein's, the DA consistently imposed conditional renewals as an initial punishment, choosing revocation only for subsequent violations.[4]

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[3] *See, e.g., Jeffrey Martin Ford, D.D.S.; Grant of Restricted Registration*, 68 Fed. Reg. 10750 (Mar. 6, 2003); *In the Matter of Mary Thomson, M.D.; Continuation of Registration with Restrictions*, 65 Fed. Reg. 75969 (Dec. 5, 2000); *Donald P. Tecca, M.D.; Continuation of Registration With Restrictions*, 62 Fed. Reg. 12842 (Mar. 18, 1997); *Vincent J. Scolaro, D.O.; Grant of Restricted Registration*, 67 Fed. Reg. 42060 (June 20, 2002); *Karen A. Kruger, M.D.; Grant of Restricted Registration*, 69 Fed. Reg. 7016 (Feb. 12, 2004); *Wesley G. Harline, M.D.; Continuation of Registration With Restrictions*, 65 Fed. Reg. 5665 (Feb. 4, 2000); *Gregory D. Owens, D.D.S.; Grant of Restricted Registration*, 67 Fed. Reg. 50461 (Aug. 2, 2002); *Scott H. Nearing, D.D.S.; Grant of Restricted Registration*, 70 Fed. Reg. 33200 (June 7, 2005); *Edson W. Redard, M.D.; Continuation of Registration With Restrictions*, 65 Fed. Reg. 30616 (May 12, 2000); *Michael Alan Patterson, M.D.; Grant of Restricted Registration*, 65 Fed. Reg. 5682 (Feb. 4, 2000); *Robert M. Golden, M.D.; Grant of Restricted Registration*, 65 Fed. Reg. 5663 (Feb. 4, 2000)

[4] *See Tecca*, 62 Fed. Reg. at 12847 (Administrator continued the registration subject to conditions requiring him to cooperate with DEA, submit to periodic performance reviews, and complete additional training); *Ford*, 68 Fed. Reg. at 10754 (Administrator continued the registration subject to conditions including random drug testing, limitations on his ability to prescribe, and that he cooperate with local DEA officials by providing information); *Harline*, 65 Fed. Reg. at 5672 (imposing conditions requiring the registrant to provide DEA copies of physician charts and to consent to DEA inspections); *Kruger*, 69 Fed. Reg. at 7018 (imposing conditions limiting registrant's ability to prescribe, requiring disclosure to DEA, and requiring submission to

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The substitution of its own reasoning for that of the DA to justify *post hoc* revocation of Chein's registration was an apparent attempt to avoid application of its own previously controlling precedent in *Morall v. DEA*, 412 F.3d 165 (D.C. Cir. 2005). *Morall*'s central teaching (that it is an abuse of discretion for the DA to depart from agency precedent without a reasoned explanation) applies perfectly to her repeat offense in this case. *Morall*, 412 F.3d at 183. The DA gave no explanation for her departure from agency precedent that preferred continued registration with conditions over revocation. Final Order at 6590-92, 6594. When the D.C. Circuit's *post hoc* rationalization is removed, there remains no sound basis for distinguishing the *Chein* case from *Morall*, 412 F.3d 165 (D.C. Cir. 2005).

As *Morall* makes clear, it is essential for an agency to explain its decision-making; it must establish a rational connection between the facts found and the ultimate decision made and it must explain its departure from precedent. 5 U.S.C. § 706; *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 44 (1983) ("in reviewing that explanation, we must consider whether the decision was based on a consideration of the relevant factors and whether there has been a clear error of judgment," *quoting Bowman Transportation, Inc. v. Arkansas-Best Freight System, Inc.*, 419 U.S. 281, 285 (1974));

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random drug testing). *See also Thomson*, 65 Fed. Reg. at 75969; *Scolaro*, 67 Fed. Reg. at 42060; *Owens*, 67 Fed. Reg. at 50461; *Redard*, 65 Fed. Reg. at 30616.

Dickinson, 527 U.S. at 155. *Morall* requires the DEA DA to explain in a reasoned manner her imposition of the draconian sanction of revocation because that decision departs from her prior cases where, upon comparable or more egregious facts, she continued the registration of first time offenders. The *Morall* Court properly refrained from adopting a *post hoc* rationalization to justify DEA's decision, focusing instead on the content within the four corners of that document. As is clear from the shift to *post hoc* rationalization in Chein's case, that approach encourages capricious decision making at the administrative level because the DA is liberated from her basic duty to explain her departures from precedent. She may then rule at her whim, according to unreasoned bias and prejudice. *Burlington Truck Lines v. United States*, 371 U.S. 156, 168 (1962); *Martin v. Occupational Safety and Health Review Comm'n*, 499 U.S. 144, 157 (1991). By adopting a *post hoc* rationalization, the D.C. Circuit stepped outside its judicial role and assumed a role Congress invests in administrative agencies at the time they render decisions. *NLRB v. Metro. Life Ins. Co.*, 380 U.S. 438, 444 (1965) ("[f]or reviewing courts [substitution of] counsel's rationale or their discretion for that of the Board is incompatible with the orderly function of the process of judicial review"). To correct the D.C. Circuit's wayward course and prevent continued abuse of discretion and arbitrary and capricious action by an agency upon whom all American physicians depend for the maintenance of their listed chemical prescription practices, this Court should intervene and reverse.

B. The D.C. Circuit Has Condoned DEA Violation of the Fifth Amendment Void for Vagueness Doctrine and the APA by Upholding DEA's Failure to Adopt a Coherent, Uniformly Applied Standard for the Regulation of Physician Dispensing to Foreign Patients with Scheduled Listed Chemicals

Medical practice has become international. American physicians of world renown provide health care services to patients resident outside the country's borders. *See, e.g.*, American Osteopathic Association, *D.O.s Go Global: Osteopathic Medicine Finding a Home Outside the U.S*;[5] Amy J. Oliver, *Internet Pharmacies: Regulation of a Growing Industry*, 28 J.L. Med. & Ethics 98 (2000); David B. Brushwood, R.Ph., J.D., *Responsive Regulation of Internet Pharmacy Practice*, 10 Annals Health L. 75, 88 (2001). As a leading expert in the field of anti-aging medicine, Edmund Chein, M.D. treats patients worldwide. He trains and works in tandem with hundreds of physicians in other countries who seek to emulate his treatment protocol.

The DA accused Chein of diversion because he dispensed schedule III controlled substances that were not narcotics without having registered as an exporter, ignoring the fact that Chein was already registered to dispense those substances to his patients. Final

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[5] *Available at*, http://www.osteopathic.org/index.cfm?PageID=ost_dogoblobal (last visited October 27, 2008).

Order at 6590; App. 73-79. Neither the statutes nor the regulations on point define lucidly what physicians who wish to prescribe to foreign patients must do to achieve DEA approval. *See* 21 U.S.C. § 822 *et seq.*; 21 U.S.C. § 951 *et seq.*; 21 C.F.R. § 1301.01 *et seq.* Complicating matters more, DEA has a history of excusing physicians who have dispensed scheduled listed drugs to foreign patients from filing formal export applications and, instead, works cooperatively with them on an *ad hoc* basis to permit and condone that dispensing. ALJ Dec. at 55 ¶ 187; App. 176-77. Without reasoned explanation, DEA chose not to cooperate with Chein but to compel him (twice) to file a formal export application, effectively baiting him for an ultimate denial of the application. ALJ Dec. at 58-59; App. 180-83. At first, so unusual was the receipt of the application that DEA's own processing staff refused to process it, noting atop it "Already have DEA #," meaning that Chein's pre-existing registration to dispense appeared to the staff to suffice. *See* ALJ Dec. at 58; Tr. at 1805; App. 180-83, 238-43. The DEA thus maintains an irrational and inconsistent regulatory regime that denies physician regulatees of minimum notice of what the law requires and of how to fulfill those requirements. The lack of a coherent DEA regulatory regime to define standards for physician dispensing in international practice invites chaos. Physicians must know with clarity what DEA expects of them before they dispense controlled substances to foreign patients.

In almost all instances to date, except in Chein's case, the DEA imposes no sanction upon physicians who dispense to foreign patients. *See Rose Mary Jacinta Lewis, M.D.; Affirmance of Immediate Suspension*, 72 Fed. Reg. 4035, 4040-41 (Jan. 29, 2007) (presenting more egregious facts than Chein's case, the DA cited, *inter alia*, export violations but the case represents the only other occasion in the Federal Register where the DA punished a physician under the export regulations). DEA admits to routinely discovering the practice after-the-fact and then informally communicating with the physician, providing cooperative guidance, without sanction and without cessation of the practice. ALJ Dec. at 55 ¶ 187; App. 176-77. In that environment void of rules, the DEA does not compel the submission of export applications by physicians nor does it punish physicians, as it did Chein, for failing to provide proof of letter perfect compliance or for past prescribing practices not in accordance with agency desires. The system now in place is arbitrary and capricious because it depends not on clear rules but on the DA's caprice in individual cases. It denies the regulated class sufficient information to discern what is required, when requirements have to be met, and how requirements must be satisfied. It epitomizes abuse of discretion and it will wreak havoc in medical practice unless DEA is compelled to explain cogently what it expects of American physicians engaged in international medical practice.

The D.C. Circuit did not address Dr. Chein's argument regarding the lack of a discernible standard for dispensing abroad. The DA did not find any evidence of actual diversion based on Chein's alleged "exportations." Instead, the DA broadly extended the language in the export statute to encompass acts occurring within the doctor-patient relationship. Final Order at 6591; App. 78-83. The DA thus failed to appreciate the unique statutory application of the term "dispense," a term of art that narrowly encompasses movement of controlled substances pursuant only to a valid, legitimate practitioner's prescription. *See* 21 U.S.C. § 802(10) ("[t]he term 'dispense' means to deliver a controlled substance to an ultimate user . . . by, or pursuant to the lawful order of, a practitioner"). Contrary to principles of statutory interpretation, the DA understood "dispensing" to be synonymous with "exporting," and then applied the export regulations to dispensing. *Id.* at 6590-91; App. 73-83. However, contrary to the DA's interpretation, dispensing and exporting are distinct acts under the CSA, each regulated in distinct subchapters, and are in fact treated differently by the DEA's application processing staff. By extending the export regulations to the practice of dispensing, the DA thus not only departed from DEA practice without reasoned explanation but also precluded an act of legitimate medical practice (the prescription of medicine directly from physicians to their patients abroad). That prohibition was beyond the scope of the statute.

Under 21 U.S.C. § 822(b), a physician's DEA registration authorizes him to dispense to his patients. The statute reads:

> Authorized activities. Persons registered by the Attorney General *under this subchapter* to manufacture, distribute, or dispense controlled substances or list I chemicals are authorized to possess, manufacture, distribute, or dispense such substances or chemicals (including any such activity in the conduct of research) to the extent authorized by their registration and in conformity with the other provisions of this subchapter.[6]

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[6] Chein's good faith belief that he was sufficiently registered to dispense to his overseas patients is not only consistent with the views of DEA's application processors but is also supported by the structure and language of the relevant provisions of the CSA as codified in Chapter 13 of Title 21 of the United States Code (USC). Chein is registered to dispense controlled substances under 21 U.S.C. § 822. As a registrant, Chein is authorized to "possess, manufacture, distribute, or dispense . . . to the extent authorized by [his] registration and in conformity with the other provisions *of this subchapter*." 21 U.S.C. § 822 (emphasis added). Sections 820-30, regarding registration of manufacturers, distributors, and dispensers of controlled substances are contained in Subchapter I of Chapter 13, while the provisions regarding import and export of controlled substances, sections 951-58, are located in Subchapter II of Chapter 13. The exemptions from registration in section 957(b) allow those in the chain of exportation, such as common carriers and warehousemen, to possess controlled substances without a registration. *See* 21 U.S.C. § 957(c). However, as a registered practitioner under section 822, Chein was already authorized to possess controlled substances.

Id. (emphasis added). Section 822 of the Statute, 21 U.S.C. § 822, does not require a separate export registration. The registration to dispense does not limit dispensing to patients resident in the U.S. Indeed, the requirements for a dispensing registration are explicitly contained in Chapter 13, Subchapter I, and the statutory language limits compliance to the "other provisions of this subchapter." *Id.* Chapter 13, Subchapter II contains the export requirements and, although referencing "manufacturers" and "distributors," includes no reference to dispensing by physicians.

The statute does not restrict the practice of medicine as the DA suggested. *See* Final Order at 6591; App. 78-83 (noting that while the CSA does not define export, the DEA has broadly defined the term in the C.F.R. to encompass "any taking out or removal . . . from the jurisdiction of the United States"). Under the maxim *inclusion unius est exclusion alterius*, where a statute enumerates the subjects, things, or acts on which it is to operate, the statute will be construed as excluding from its effect all those subjects or things not expressly mentioned. *See generally New Jersey v. Delaware*, 128 S.Ct. 1410, 1433 (2008). Thus, the failure to mention exporting in Subchapter I, and the attendant failure to reference dispensing in Subchapter II, reveals that dispensing was given unique statutory treatment. *See Saint Peter's University Hospital v. Lacy, M.D.*, 878 A.2d 829, 838-39 (N.J. 2005) (stating that the court's "conclusion is supported further by the unquestioned proposition that when the Legislature expressly includes a requirement in one subsection and excludes that same requirement in other subsections of the same general statute, we need not strain to import that requirement where it is not").

This Court previously explained that Congress "was concerned that the drug laws not impede legitimate research and that physicians be allowed reasonable discretion in treating patients and testing new theories." *United States v. Moore*, 423 U.S. 122, 143 (1975); *see also* Joranson and Gilson, Controlled Substances, Medical Practice and the Law, *Psychiatric Practice Under Fire* (1994). DEA lacks authority to dictate what constitutes the legitimate practice of medicine. *See Dispensing Controlled Substances for the Treatment of Pain*, 71 Fed. Reg. 52716, 52717-18 (Sep. 6, 2006) (describing DEA's regulatory role concerning the dispensing of pain medication); *Gonzales v. Oregon*, 126 S.Ct. 904, 925 (2006). By preventing Chein's exports, the DA wedged the agency between a physician and his legitimate treatment of his patients resident overseas.

Chein is a physician dispensing solely to his patients. He does not dispense beyond personal use quantities and does not dispense for resale. Final Order at 6591; App. 78-83. The typical manufacturer or distributor, by contrast, exports large quantities for commercial resale and use. Chein is subject to all rules and ethical guidelines of the medical profession and does not deliver indiscriminately but rather prescribes small quantities for individual use to his patients after medical evaluation and testing. Chein's treatment of patients resident abroad remained within the legitimate practice of medicine. The practitioner's registration to dispense governs a physician patient relationship even where the patient is not a U.S. resident.

Chein was reasonable in believing he only had to comply with the requirements of Subchapter I. The DA's counterargument failed in its logic as the CSA would not become null if physicians were permitted to dispense non-narcotic schedule III substances to their patients abroad, because any movement of controlled substances outside the confined doctor-patient relationship is not "dispensing" within the meaning of the statute. 21 U.S.C. § 802. Subchapter I references registrants who dispense, whereas Subchapter II is a general import and export statute. Chein rightfully adhered to the particular statutory restrictions applicable to dispensing physicians, and understandably thought the CSA Section not concerning physicians was inapplicable. The DEA's export application processing staff apparently held the same view, electing not to process Chein's application because he already had a physician registration to dispense. *See* ALJ Dec. at 58; Tr. at 1805; App. 180-83, 238-43. Because dispensing is part of the practice of medicine, insulated from the dangers of commercial exportation, DEA should possess no more authority over dispensing to foreign patients than it has over physicians who dispense across state lines.

In addition, the actual export requirements remain unclear and confusing. The language of 21 U.S.C. § 953(e) does not require physicians to obtain export registration for dispensing schedule III non-narcotic substances to their patients resident overseas. *See* Final Order at 6591; App. 78-83 (the DA admitted, "it is true that [Dr. Chein] was not required to obtain an Export Permit for either the testosterone or phentermine he exported," but improperly concluded the law still required an export registration). Under the DA's logic, based on 21 U.S.C. § 957(a)(2), Chein still needed an export registration and also needed to file an Export Declaration (Form 236, see below) and submit the documentary proof required by the statute. *Id.* If the DA interprets the lack of language requiring an export *permit* to mean Chein did not in fact need an export permit, then the absence of language in the same statute requiring an export registration suggests that Chein did not need an export registration. The language of § 953(e) deals specifically with the exportation of schedule III non-narcotics, and it contains no reference to § 957 or any mention of an export registration. By contrast, § 953(a)(5), dealing with narcotics, includes reference to the need for a separate export registration. Under the tenets of statutory construction discussed above, Chein correctly interpreted the missing language in § 953(e) as evidence that export of schedule III non-narcotics *without a separate export registration* was lawful.

As further evidence of the statute's inapplicability, the DA argued that Chein must give notice of so-called exports using a DEA Form 236, which is entirely inapplicable on its face to Chein's situation. *See* 21 C.F.R. § 1312.21(b); Final Order at 6591; App. 78-83. Form 236 requires the name and address of a "foreign consignee/consignor." *Id.* at n.20; App. 82. Since Chein's end users are his own patients, no consignee or consignor exists. Those terms are used to describe persons from whom and to whom goods are shipped for sale to third parties. *See, e.g., Bank of California v. Thornton-Blue Pacific, Inc.*, 53 Cal. App. 4th 841, 847 (1997); *Tele-King Distributing Co. of Los Angeles v. Wyle*, 218 F.2d 940 (7th Cir. 1955). A form designed for large commercial shipments for resale is inapplicable on its face to this case – a case of a doctor dispensing to a patient in the usual course of medical practice. DEA agents testified that 99.9% of the individuals with whom the export office communicates are businesses exporting listed chemicals. Tr. at 2338; App. 245-47. The export registration provisions are facially inapplicable to dispensing physicians.

Adding to the uncertainty, DEA agents misled Chein Although Chein correctly believed he did not need a separate export registration, he accommodated the DEA, at the urging of agent DeSantis, and submitted an export application, not once but twice. ALJ Dec. at 79; App. 208-09. DEA rejected the application because Chein "Already [had a] DEA #." ALJ Dec. at 58; Tr. at 1805; App. 180-83, 238-43. The DEA then refunded Chein's credit card, despite the application statement that the fee was nonrefundable. *Id.* No agent informed Chein of the rejection of his application, or DEA's reasons for refusing the application. ALJ Dec. at 81; App. 211-12. Agent DeSantis also faxed a copy of 21 U.S.C. § 953(a) to Chein, presumably to convince him that he needed a registration, and later DeSantis at hearing admitted that Section 953(a) applied only to narcotics and that her view that Chein needed to abide by that section was in error. ALJ Dec. at 57, 79; Tr. at 949; App. 181-83, 208-09, 231-32. Even DEA's field agents and processing staff were confused about what DEA required of physicians treating their foreign patients.

The statutory language and accompanying regulations, as well as the conflicting actions of DEA regulatory agents, created a confusing, incoherent, regulatory morass, but the law on point requires clarity and predictability. *Grayned v. City of Rockford*, 408 U.S. 104, 108-09 (1972). A statute or standard is void for vagueness if ordinary persons using common sense would not be notified that certain conduct puts them in legal peril. *Id.* The lack of clarity denied reasonable notice to all the regulated class of what the law required. *Id.* at 108-09 (stating person of ordinary intelligence must be given reasonable opportunity to know what is prohibited and act accordingly). That incoherent regulatory regime deprives physicians dispensing schedule III non-narcotic substances to their patients resident abroad, like Chein, of fair notice. That incoherence denies all physician regulatees freedom from DEA's arbitrary and capricious application of the export regulations at the whim or caprice of the DA. *Grayned*, 408 U.S. at 109 (explaining that besides risk that a vague statute does not give person fair notice, a vague statute also does not give enough guidance to those enforcing the statute and risks the enforcement being arbitrary and discriminatory).

With the practice of medicine now international, we can expect ever more dispensing in the course of care to patients who reside abroad. Unless this Court intervenes and compels DEA to develop clear standards, prescription of controlled substances to patients resident internationally will continue to occur in a hopelessly confused regulatory environment. DEA's vague and irrational regime violates the Fifth Amendment Due Process Clause and the APA prohibition on arbitrary and capricious agency action. The D.C. Circuit's failure to engage that critical argument was plain error in an area of urgent clinical need for clarity and certainty. This Court should intervene and reverse.

C. The D.C. Circuit Condoned a Violation of the Administrative Procedure Act's Arbitrary and Capricious and Abuse of Discretion Standards When It Upheld DEA's Unreasoned Departure From the DA's Consistent Practice of Granting Conditional Renewals in Her *Initial* Physician Registration Decisions, Reserving Revocation to *Subsequent* Decisions that Evaluate Those Renewals

The D.C. Circuit missed an essential distinguishing principle arising from DEA precedent that made the DA's decision to revoke Chein's registration remarkable and an abuse of discretion under 5 U.S.C. § 706(2)(A). In her *initial* decisions on physician registrations, the DA has granted conditioned renewals as a matter of course, creating an effective probationary period where she observes the physician's performance to determine, in a *subsequent* decision, whether revocation is warranted.[7] The DA issued

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[7] *See, e.g., Jeffrey Martin Ford, D.D.S.; Grant of Restricted Registration*, 68 Fed. Reg. 10750 (Mar. 6, 2003); *In the Matter of Mary Thomson, M.D.; Continuation of Registration with Restrictions*, 65 Fed. Reg. 75969 (Dec. 5, 2000); *Donald P. Tecca, M.D.; Continuation of Registration With Restrictions*, 62 Fed. Reg. 12842 (Mar. 18, 1997); *Vincent J. Scolaro, D.O.; Grant of Restricted Registration*, 67 Fed. Reg. 42060 (June 20, 2002); *Karen A. Kruger, M.D.; Grant of Restricted Registration*, 69 Fed. Reg. 7016 (Feb. 12, 2004); *Wesley G. Harline, M.D.; Continuation of Registration With Restrictions*, 65 Fed. Reg. 5665 (Feb. 4, 2000); *Gregory D. Owens, D.D.S.; Grant of Restricted Registration*, 67 Fed. Reg. 50461 (Aug. 2, 2002); *Scott H. Nearing, D.D.S.; Grant of Restricted Registration*, 70 Fed. Reg. 33200 (June 7, 2005);

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conditional renewals in cases where the allegations were comparable to Chein's and, indeed, on facts that were far more egregious than those alleged here. *See, e.g., Saxton*, 69 Fed. Reg. 7016 (registrant prescribed medication in a manner that placed his patients at risk; liberally prescribed anabolic steroids and controlled substances without a legitimate medical purpose; and provided patients prescriptions knowing they abused the medication); *Tecca*, 62 Fed. Reg. at 12842 (registrant prescribed controlled substances to undercover officers for no legitimate reason on eight separate occasions; registrant dispensed 1,640 dosages of codeine to one patient within a three-month period); *Ford*, 68 Fed. Reg. at 10750 (registrant shared narcotics with friends and family, and was convicted numerous times of drug-related criminal offenses involving the controlled substances he dispensed).

The DA departed from that precedent in this case. Chein had not previously appeared before the DA. Consistent with precedent he should have been granted conditional renewal of his registration and an opportunity to show the DEA that he can dispense non-narcotic controlled substances in accordance with DEA's wishes.

Edson W. Redard, M.D.; Continuation of Registration With Restrictions, 65 Fed. Reg. 30616 (May 12, 2000); *Michael Alan Patterson, M.D.; Grant of Restricted Registration*, 65 Fed. Reg. 5682 (Feb. 4, 2000); *Robert M. Golden, M.D.; Grant of Restricted Registration*, 65 Fed. Reg. 5663 (Feb. 4, 2000).

The DA's revocation *in her first consideration of the Chein* matter was a radical departure from the customary DEA pattern of decision. That revocation was a deviation that occurred without explanation, thus offending the Administrative Procedure Act and this Court's decision in *Morall*. *Morall*, 412 F.3d at 182-83; 5 U.S.C. § 706(2)(a). In typical or more egregious cases, the DA imposed probationary conditional renewals and then evaluated the period of probation to discern if violations continued (occasionally, albeit inconsistently, revoking thereupon if so found).[8]

No DEA precedent supports revocation on similar facts and circumstances *in the DA's first review of a physician's registration*. The DA offers none in her decision in the *Chein* case. Moreover, the factors relied upon by the D.C. Circuit to revoke Chein's registration are the same factors applied in precedent to continue registrations with conditions.[9] Those

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[8] *See, e.g.*, *Ford*, 68 Fed. Reg. at 10754; *Thomson*, 65 Fed. Reg. at 75969; *Tecca*, 62 Fed. Reg. at 12842; *Scolaro*, 67 Fed. Reg. at 42060; *Kruger*, 69 Fed. Reg. at 7016; *Harline*, 65 Fed. Reg. at 5665; *Owens*, 67 Fed. Reg. at 50461; *Redard*, 65 Fed. Reg. at 30616.

[9] *See Tecca*, 62 Fed. Reg. at 12847 (Administrator continued the registration subject to conditions requiring him to cooperate with DEA, submit to periodic performance reviews, and complete additional training); *Ford*, 68 Fed. Reg. at 10754 (Administrator continued the registration subject to conditions including random drug testing, limitations on his ability to prescribe, and that he cooperate with local DEA officials by providing information); *Harline*, 65 Fed. Reg. at 5672 (imposing conditions requiring the registrant to provide DEA copies of physician charts and

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factors do not apply when the DA revokes a registration.

D. Under 21 U.S.C. § 823(a)-(f) and *Universal Camera Corp.*, It Was Incumbent Upon the D.C. Circuit to Analyze in a Written Opinion All Elements Favoring the Regulatee Under the Statute's Multi-Factor Test

The D.C. Circuit failed to evaluate the elements of the multi-factor test in 21 U.S.C. § 823(a)-(f) that favored Chein. In *Universal Camera Corp. v. NLRB*, 340 U.S. 474 (1951), this Court explained that in reviewing agency actions under the substantial evidence test, such as in this case (where the DA's decision hinges on an evaluation under the multi-factor test in 21 U.S.C. § 823 (a)-(f)), the court must review all contradictory evidence and argument presented by the petitioner which may cast doubt on the agency's decision. *Id.* at 487. The D.C. Circuit referenced in passing Chein's seven arguments under Section 823, but did not provide a written opinion evaluating a single one of them. *Chein,* 533 F.3d at 835 (App. 16-18). That failure violates *Universal Camera Corp.* and the statutory mandate in Section 823.

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to consent to DEA inspections); *Kruger*, 69 Fed. Reg. at 7018 (imposing conditions limiting registrant's ability to prescribe, requiring disclosure to DEA, and requiring submission to random drug testing).

Effective judicial review of an agency decision that is predicated on a statutory scheme involving a multi-factor balancing test, as in Section 823, depends on judicial evaluation of evidence against the agency's decision under that test. 5 U.S.C. § 702; *Dickinson*, 527 U.S. at 155. The Administrative Procedure Act requires meaningful judicial review in such instances. *See* 5 U.S.C. § 702. A written opinion is essential because a regulatee cannot discern the legality of the balancing process without reasoned explanation of what the law requires. Future defendants are left without a discernible standard to guide them. This Court should intervene and reverse.

CONCLUSION

The D.C. Circuit has failed to exercise judicial review to compel the DEA to establish clear standards to govern physician dispensing to their patients resident overseas and to establish an intelligible principle to distinguish when physicians' registrations will be continued with conditions rather than revoked outright. Medical practice indispensable to the welfare of patients depends on clear standards and cannot exist without destructive chaos in an environment where the DEA fails to give physician registrants coherent standards that define what conduct is expected, when compliance is required, and how compliance is to be achieved. The D.C. Circuit's decision in *Chein* failed to compel DEA compliance with the APA, with this Court's administrative law precedent, with the D.C. Circuit's *Morall* decision, and with the Fifth Amendment. The D.C. Circuit thus exacerbated the agency's underlying regulatory incoherence problem and invited more of the same to the grave detriment of patients and to the disability of physician medical practice. This Court should intervene, reverse, and restore stability in the regulation of physician dispensing of controlled substances at home and abroad.

Respectfully submitted,

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United States Court of Appeals
FOR THE DISTRICT OF COLUMBIA CIRCUIT

Argued January 15, 2008 Decided July 22, 2008

No. 07-1051

EDMUND CHEIN, M.D.,
PETITIONER

v.

DRUG ENFORCEMENT ADMINISTRATION *ET AL.*,
RESPONDENTS

On Petition for Review of an Order of the
United States Drug Enforcement Agency

Jonathan W. Emord argued the cause for the petitioner. *Charles M. Sevilla* was on brief.

Teresa A. Wallbaum, Attorney, United States Department of Justice, argued the cause for the respondent.

Before: SENTELLE, *Chief Judge*, and HENDERSON and RANDOLPH, *Circuit Judges*.

Opinion for the court filed by *Circuit Judge* HENDERSON.

KAREN LECRAFT HENDERSON, *Circuit Judge*: Edmund Chein (Chein) seeks review of the revocation of his practitioner's registration and the denial of his application for a registration to export Schedule III non-narcotic and Schedule IV controlled substances – both actions taken by the United States Drug Enforcement Administration (DEA). The DEA Deputy Administrator (DA) found that it was not in the public interest to renew Chein's practitioner's registration or to grant him an export registration because he provided several undercover agents with anabolic steroids to enhance athletic performance; committed a number of record keeping violations; ordered controlled substances using an unauthorized DEA registration number; illegally imported controlled substances from an unregistered Mexican pharmacy and illegally shipped controlled substances to hundreds of overseas patients without a DEA export registration. Moreover, the DA found that Chein continued to dispense controlled substances even after his DEA registration had been suspended and continued to export controlled substances even after being informed by DEA that it was illegal to do so. For the reasons set forth below, we deny his petition.

I.

Chein is the owner of the Palm Springs Life Extension Institute (PSLEI) in Palm Springs, California. He is a physician, having graduated in 1980 from the American University of the Caribbean School of Medicine. He also holds a law degree. Edmund Chein, M.D.; Revocation of Practitioner's Registration, Denial of Application for Exporter's Registration, 72 Fed. Reg. 6580, 6582 (Feb. 12, 2007). Chein is licensed to practice medicine in California and in Utah and was, before the proceeding under review, registered with DEA to dispense controlled substances (Schedules II through V). *See* Gov't Ex. (GX) 2. Chein purports to be "one of the world's leading authorities in the field of anti-aging medicine." Chein Br. 8. He believes that "every adult experiences hormone level reductions over time and those reductions coincide with outward and inward signs of aging." *Id.* Chein claims that "through gradual increases in hormones to those approximating youthful levels, along with exercise and diet modification, individuals can slow the process of aging and delay the onset of, or prevent, age-related conditions." *Id.* This is accomplished through the "administration of very low doses of hormones over an extended period of time, accompanied by continued monitoring of baseline hormone levels until they slowly rise to approximate levels of a healthy young adult." *Id.* at 9. Chein calls the practice "total hormone replacement therapy." (THRT). *Id.* at 8. According to Chein, THRT differs from traditional gastroenterology in that "[a physician] administers hormones when they are less than those common in people of comparable age; [in] THRT, by contrast, [a physician] administers hormone[s] when levels drop below those of a typical healthy young adult." *Id.* at 8-9. He asserts that "[n]o patient has ever complained" about his practice. *Id.* at 9.

Chein has had a tense history, however, with the California Medical Board (CMB), DEA and law enforcement in general.[1] The CMB has taken action against Chein's medical license three times. In 1995, the CMB revoked Chein's license, stayed the revocation and put him on probation for "failing to obtain a . . . business license and for falsely advertising himself as a physician and lawyer when he had never obtained a license to practice law." *Chein v. Med. Bd. of Cal.,* No. 00CS00319, at 4 (Cal. Super. Ct. Nov. 9, 2000); GX 125. In 2000 the CMB again revoked Chein's medical license, charging that he had "prescribed human growth hormone for a patient without medical indication and . . . had made false and misleading statements in certain publications and advertisements about hormone replacement therapy." *Id.* at 1. Chein challenged the revocation in state court and was successful in part. *Id.* at 17. The CMB and Chein ultimately entered into a settlement agreement revoking Chein's license, staying the revocation and suspending Chein from the practice of medicine for

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[1] In 1996, Chein was convicted in California state court of three counts of criminal perjury for exaggerating his qualifications as an expert witness in two civil lawsuits, *see* In re Edmund Chein, M.D., No. 02-9, 02-43, Recommended Findings of Fact, Conclusions of Law, and Decision of the Administrative Law Judge (July 28, 2005) (ALJ Dec.) ¶ 48; GX 33; Tr. 221. Chein sought habeas corpus relief in district court, *id.*, and the Ninth Circuit reversed the district court's denial of Chein's petition. *Chein v. Shumsky,* 373 F.3d 978, 993 (9th Cir. 2004) (en banc).

10½ months "with credit for 10½ months already served." GX 113, at 4; GX 125, at 2.

In 2002, the CMB initiated a third disciplinary action against Chein alleging, *inter alia,* that he had "prescrib[ed] . . . [human growth hormone] without a good faith examination and medical indication," "fail[ed] to maintain adequate and accurate records," "obtained controlled substances by deceit, misrepresentation and subterfuge" and "dispensed controlled substances without proper privileges." In re Edmund Chein, M.D., No. 19-2000-107723, Accusation ¶¶ 18, 21-23, 31 (filed Aug. 15, 2002). The CMB and Chein eventually settled this dispute as well, noting that the settlement "[was] intended to resolve," in addition to the CMB's disciplinary action, "any disciplinary action taken by another state or the federal government based on the conduct alleged in the [August 15, 2002 Accusation]." In re Edmund Chein, M.D., No. 19-2000-107723, Stipulated Settlement & Disciplinary Order 2-3 (filed Sept. 22, 2005). Under the settlement, the CMB revoked Chein's medical license, stayed the revocation and placed Chein on probation for five years.[2]

Chein has also had a long history with DEA. In 1994 and 1995, investigators from DEA, the Food and

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[2] The settlement occurred after the DEA Administrative Law Judge (ALJ) issued her recommendation in this case, *see* ALJ Dec. ¶ 55, but the DA noted it in her decision. *See* Chein, 72 Fed. Reg. at 6583 n.4 (citing 5 U.S.C. § 556(e)).

Drug Administration (FDA) and the United States Customs Service (Customs) conducted a series of undercover visits to PSLEI. During the visits Chein dispensed and prescribed Human Growth Hormone (HGH) and anabolic steroids[3] to the investigators ostensibly to improve athletic performance.[4] On May

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[3] An anabolic steroid is a Schedule III controlled substance. *See* 21 U.S.C. § 812(c) (Schedule III). While HGH is not included as a scheduled controlled substance, *see id.*; *see also* 72 Fed. Reg. at 6582 n.3, federal law prohibits knowingly distributing, or possessing with intent to distribute, HGH for any use in humans except as authorized by the Secretary of the United States Department of Health and Human Services and pursuant to a physician's order. 21 U.S.C. § 333(e).

[4] The first visit occurred on September 9, 1994. Brannon Affidavit ¶ 18. An undercover FDA Special Agent (SA) visited Chein posing as a rugby player who wanted to "build up" to avoid injury. *Id.* ¶ 19(d). Chein informed the SA that he could use HGH to "build muscle, endurance, speed, strength and muscle mass," and that "[i]n the next decade, competitive sport athletes will be doing human growth hormone and natural testosterone." *Id.* ¶ 19(d)(ii), (vi). Chein drew blood from the SA to test HGH and testosterone levels; during the same office visit, and without knowing the blood test results, Chein dispensed HGH to the SA. *Id.* ¶ 19(e)-(h). He also provided a prescription for insulin syringes. *Id.* ¶ 19(f). Chein subsequently dispensed several additional shipments of HGH to the undercover SA via Airborne Express. *Id.* ¶¶ 21-23.

On October 17, 1994, another FDA undercover SA visited Chein. The SA informed Chein that he "had experienced difficulties in putting on muscle mass while weight-lifting." *Id.* ¶ 25(d). He also told Chein that he had taken steroids previously "but wanted a safer alternative." *Id.* Chein informed the SA that "[t]he latest development in 'body-building science or medicine' involved both human growth hormone and natural testosterone administered through the skin by means of a patch or gel, both

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having a synergistic effect in building up lean muscle." *Id.* ¶ 25(d)(iii). Chein drew blood to test the SA's testosterone and HGH levels; again, during the same office visit, and without knowing the blood test results, Chein prescribed insulin syringes, testosterone gel and HGH for the SA. *Id.* ¶ 25(e)-(g).

On March 17, 1995, an undercover Customs SA visited Chein posing as a competitive weightlifter. *Id.* ¶ 36. The SA explained that "he was interested in human growth hormone for gaining strength for competitive powerlifting and gaining strength, had been taking Anadrol (an anabolic steroid), but wanted [HGH] because he was losing to guys who are 'on the juice.'" *Id.* ¶ 37(c). Chein told the SA that "[a]fter 1990, the whole body-building industry had switched to natural testosterone, and the 'new power lifting people use testosterone and HGH.'" *Id.* ¶ 37(d)(i). Chein claimed that the hormone treatments could "increase his capacity" by 75-100 lbs "within a month." *Id.* ¶ 37(d)(viii). Moreover, he informed the SA that "[t]he human growth hormone and testosterone would not show up in drug testing at competitions if [he] followed Chein's instructions." *Id.* ¶ 37(d)(iv). Again, Chein ordered a blood test, and, again, before the result was available, Chein gave the SA a vial of HGH and a prescription for testosterone gel, explaining "I would rather see you abuse this than abuse Anadrol." *Id.* ¶ 37(d)(vii).

On July 20, 1995, a DEA SA visited Chein posing as a power lifter training for the Olympics. *Id.* ¶ 38(c). Chein ordered a blood test for testosterone and HGH levels. *Id.* ¶ 38(d)(h). He explained that the treatment was to be "[o]ff the record" because he "had a strict agreement with the U.S. Attorney's office not to give [HGH] to people who didn't need it or to simply help them 'build up strength' and that they would . . . 'handcuff [him]'" if he did. *Id.* ¶ 38(e)-(f). He then joked with the SA, "[i]f you are [a federal agent], I'm dead." *Id.* ¶ 38(e). Chein planned to put the SA on a regimen of four different hormones – testosterone, HGH, insulin and dehydroepiandrosterone (DHEA) – "all of which would help with weight lifting." *Id.* ¶ 38(e)(v). He further explained that the testosterone "would not show up in a drug test related to power lifting if [the SA] stopped taking [it] two

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23, 1996, FDA obtained a search warrant for PSLEI. *See* Search Warrant 1, No. 96-1101 (May 23, 2006). FDA and DEA investigators who conducted the search seized various anabolic steroids. Tr. 132. Although DEA regulations require a registrant to maintain purchase records, an inventory and a dispensing log at his registered address; *see, e.g.*, 21 C.F.R. §§ 1304.03-.04, no such records were found during the search. Tr. 134.[5]

On July 20, 2000, Chein applied to renew his DEA practitioner's registration. *See* GX 1. Because Chein's California medical license was revoked at the time, his application received close scrutiny. On January 31, 2001, DEA Diversion Investigator (DI) Doris DeSantis, accompanied by DI Linda Martin, visited PSLEI to interview Chein, inspect his clinic and review his records. Tr. 263. Chein was not there

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days before" the test. *Id.* ¶ 38(c)(iv). Chein provided the SA with a one-month supply of HGH and prescriptions for the other hormones. He told the SA that, if the blood test result "came back low," he would ship additional HGH. *Id.* ¶ 38(c)(ii).

For his part, Chein argues that he did not improperly prescribe and/or dispense controlled substances to the undercover officers. He claims that "[a]thletes, particularly those who engage in endurance exercise training, commonly suffer from low testosterone levels" and that he provided HGH and testosterone to the investigators "[b]ased on each patient's respective descriptions of their physical regimens and complaints." Chein Br. 11-12.

[5] The record does not indicate that DEA took any disciplinary action against Chein following the undercover visits or the 1996 search. *Cf.* Tr. 113 (noting that investigations "never resulted in any kind of activity" by DEA).

at the time and the two met instead with Darryl Garber – another physician practicing at PSLEI. Garber informed DI DeSantis that he could not provide the biennial inventory and dispensing logs because they were stored electronically and none of the employees on duty knew how to access PSLEI's computer system. *Id.* at 268-69. Another PSLEI employee informed DI DeSantis that the purchase invoices were stored off-site with PSLEI's accountant. *Id.* at 273. Garber was eventually able to provide only two invoices, both for the purchase of phentermine (a Schedule III controlled substance). *Id.* at 275-76. DI DeSantis informed Garber that DEA regulations require records to be readily available for inspection and copying and that invoices be stored on-site. *Id.* at 274; *see also infra* note 6.

Five days later, DI DeSantis and DI Martin returned to PSLEI to review the records that were not available during their earlier visit. *Id.* at 277. Again, Chein was not present. *Id.* at 279. Garber asked the investigators to wait while he retrieved the records. After two or three hours he returned with a one-page computer generated inventory report, *id.* at 281; GX 8, dispensing logs for phentermine and various forms of testosterone, *id.* at 284; GX 9-16, and four purchase invoices for phentermine, *id.* 331-33; GX 17.[6] The documents revealed

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[6] DEA regulations provide that financial and shipping records (such as invoices and packing slips) may be kept off-site (e.g., with an accountant) *only* if the registrant has notified the DEA in writing of his intent to do so. 21 C.F.R. § 1304.04(a).

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several irregularities. DEA regulations require a registrant to maintain most records for two years "for inspection and copying" by DEA employees, 21 C.F.R. § 1304.04(a); however, the dispensing logs Garber produced covered only the seven-month period from July 1, 2000 to February 5, 2001. *See* Tr. 286-87; GX 9-16. In addition, the dispensing logs indicated that during the seven-month period, PSLEI physicians had dispensed controlled substances 317 times to patients in foreign countries, including France, Germany, Great Britain, Spain, Switzerland, China (Hong Kong), Indonesia, Japan, South Korea and Canada; *see* GX 10-12, 15, 16. Neither Chein nor Garber had an export registration required to dispense overseas. *See* GX 2; *see also* 21 U.S.C. §§ 957 &

Moreover, DEA regulations require that "[i]nventories and records of controlled substances listed in Schedule III, IV, and V shall be maintained either separately from all other records of the registrant or in such form that the information required is *readily retrievable* from the ordinary business records of the registrant." *Id.* § 1304.04(f)(2) (emphasis added). A "readily retrievable" record is "kept by [an] automatic data processing system[ ] or other electronic or mechanized recordkeeping system[ ] in such a manner that [it] can be separated out from all other records *in a reasonable time*." *Id.* § 1300.01(b)(38) (emphasis added). Chein challenged DI DeSantis's view of "readily retrievable" as "instantaneous" and the DA acknowledged that DI DeSantis applied the incorrect standard and, accordingly, did not use the 2-3 hour delay in her decision. *See* 72 Fed. Reg. 6593 ("Respondent is correct that this regulation does not require that records be 'instantaneously produced.' . . . Accordingly, there is no basis to conclude that the inventory and dispensing records were not readily retrievable. . . .") (citation omitted).

958. Moreover, some shipments went to countries where the products were illegal. *See, e.g.*, GX 38(c) (Garber acknowledged that "[i]n Japan and Korea it is against the law to prescribe Anabolic Steroids and Phentermine for the purpose of Anti-Aging Medicine." (citations omitted)); *see also* 21 U.S.C. § 953(e) (registered exporter required to file export declaration with DEA indicating "importation is not contrary to the laws or regulations of the country of destination" for each shipment). The dispensing logs Garber produced indicated that PSLEI physicians regularly dispensed various forms of testosterone, *see* GX 9-16, but Garber did not provide any purchase invoices therefor. Tr. 334. Finally, the four phentermine purchase invoices indicated that PSLEI employees had been ordering the controlled substance with an unauthorized DEA registration number. Each of the invoices contained the DEA registration number of Connie Chein, Chein's physician sister. *See* GX 17. Although Connie Chein owned PSLEI for approximately 10½ months during 2000 when her brother's California medical license was revoked,[7] she denied that she gave her

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[7] Connie Chein bought PSLEI from her brother because under California law only a licensed physician can own a medical facility. *See* Tr. 1087 (testimony of Connie Chein). Chein sold PSLEI to his sister around February 16, 2000 – two days before the CMB revoked his medical license. *See* ALJ Op. ¶ 24. After the court vacated the revocation, Connie Chein sold PSLEI back to Chein in December 2000. Tr. 1087. Although Connie Chein owned PSLEI during most of 2000, there is substantial record evidence indicating that Chein remained in control of PSLEI. *See, e.g.*, GX 28, at 14 (Connie Chein visited clinic only

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brother permission to use her DEA registration or that she was aware that anyone at PSLEI had used her registration to order controlled substances. *See* GX 28.

On March 9, 2001, DI DeSantis telephoned Garber at PSLEI to inquire about the shipments of controlled substances listed in the dispensing logs outside the United States. *See* Tr. 506-07. Garber confirmed that PSLEI was shipping controlled substances overseas. *Id.* at 507; *see also* GX-25. At that time DI DeSantis instructed Garber to immediately cease the shipments because no one at PSLEI had a DEA export registration. *Id.* at 508.[8] Later that day, PSLEI staff faxed DI DeSantis copies of purchase invoices for testosterone which had not been produced during her February 5, 2001 visit. Tr. 516-18. Again, the records appeared to be incomplete. The earliest invoice was dated November 20, 2000, *see* GX 20(k); however, the dispensing records indicated that testosterone had been dispensed for

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once); GX 96, at 32 (correspondence manifesting Chein's approval required prior to shipment of prescription); GX 105, at 36 (Chein ordered shipment of phentermine to patient in Japan); GX 107, at 23 (Chein ordered duplicate shipment of prescription); GX 136, at 14 (Chein described special handling requirements for shipments to Japan).

[8] In April 2001, Chein applied for a registration to export Schedule III non-narcotic and Schedule IV controlled substances but neither that application nor a second one was ever processed. GX 48; *see also* GX 39.

several months before November 2000. *See* GX. 15, at 23-26.[9]

On August 23, 2001, DI DeSantis and DI Violeta Willmont finally met with Chein. Tr. 546-48. Chein acknowledged not having a DEA export registration; however, he claimed that because he was shipping controlled substances directly to overseas physicians, he did not need an export registration. *Id.* at 554.[10] He told DI DeSantis that he had continued to export controlled substances despite her earlier instruction to Garber. *Id.* at 557. Chein told DI DeSantis that he did not plan to stop exporting until "he received something in writing" from DEA. *Id.* at 558. He did not tell her that he had applied for an export registration. *Id.* at 658. During the meeting Chein provided her with additional purchase invoices for controlled substances. One of the invoices, dated June 26, 2001, was for the purchase of 120 units of Depo-testosterone and 40 units of Decadurabolin (both Schedule III controlled substances) from a pharmacy in Tijuana, Mexico. *See* GX 22; Tr. 573. Chein was not then (or since) registered with DEA as an importer. GX 2; Tr. 167. On August 31, 2001, DI DeSantis instructed Chein by fax that, because he was not registered to import or export controlled substances, he "must immediately cease all acitivity (sic) in these areas as previously instructed." *Id.*

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[9] At least one of the purchase invoices used Connie Chein's DEA registration number. *See* GX 20(j).

[10] Chein's dispensing log indicates that, contrary to his claims, he shipped controlled substances directly to patients overseas. *See, e.g.*, GX 87 (dispensing log for testosterone gel showing shipments to patients in Japan).

On November 7, 2001, DEA issued an order to show cause requiring Chein to show why his practitioner's registration and his pending application for renewal should not be denied on the ground that his continued registration was inconsistent with the public interest under 21 U.S.C. §§ 823(f) and 824(a). GX 26. DEA also issued a notice of immediate suspension informing Chein that his registration was immediately suspended as an imminent danger to the public health and safety under 21 U.S.C. § 824(d). *Id.* DI DeSantis delivered both documents to PSLEI on November 12, 2001, Tr. 590, and, while there, inspected additional purchase invoices. One invoice dated March 26, 2001 indicated that two kilograms of testosterone had been purchased using Connie Chein's DEA registration. GX 45(a). Three invoices indicated that Garber had been receiving shipments of testosterone at his home and not at his registered address (i.e., PSLEI) in violation of 21 U.S.C. § 822(e) and 21 C.F.R. § 1201.12. *See* GX 45(b), (c), (d) & (g).

Subsequently DI DeSantis conducted three "trash runs" (searching garbage left for collection) at PSLEI. Tr. 686. She found paperwork showing Chein continued to export controlled substances even after she had ordered him to cease further exporting. *See, e.g.,* GX 70 (Oct. 24, 2001 invoice for shipment of phentermine and testosterone to patient in Japan); GX 73 (Oct. 29, 2001 instruction, signed by Chein, ordering shipment of testosterone to second patient in Japan). Following these discoveries, DEA obtained an administrative inspection warrant for PSLEI. GX 82. DEA agents executed the warrant on March 13, 2002, seizing PSLEI's dispensing logs, patient records for approximately 100 overseas patients and samples of controlled substances. Tr. 721, 764, 811. The records showed that Chein regularly exported controlled substances for almost three months after DI DeSantis first instructed him to stop in August 2001, *see, e.g.*, GX 84-88, and that several of the exports took place even after Chein received DEA's notice of immediate suspension. GX 84, at 3-4 (noting eight exports by Chein on November 13, 2001 and five on November 14, 2001).

A DEA Administrative Law Judge (ALJ) held a hearing on January 28-February 6, September 9-10 and December 9-11, 2003. On July 28, 2005, the ALJ issued her recommended decision. In re Edmund Chein, M.D., No. 02-9, 02-43, Recommended Findings of Fact, Conclusions of Law, and Decision of the Administrative Law Judge (July 28, 2005) (ALJ Dec.). The 82-page decision concluded that Chein's continued registration was against the public interest and also recommended that his application for an export registration be denied. ALJ Op. 82. (Three years earlier, on May 24, 2002, DEA had issued a second order to show cause directing Chein to show cause why his application for an export registration should not be denied.) *See* ALJ Op. 1. On February 12, 2007, the DA issued the final agency order revoking Chein's practitioner's registration and denying his pending export registration application. 72 Fed. Reg. at 6595. Chein then filed a timely petition for review pursuant to 21 U.S.C. § 877.

II.

Chein raises a host of objections to the DA's analysis as well as to the procedure employed during the ALJ hearing.[11] We have considered all of Chein's

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[11] Chein raises the following objections:

1. The DA revoked his registration when she had not revoked other physicians' registrations in analogous circumstances, relying on *Morall v. DEA*, 412 F.3d 165, 167 (D.C. Cir. 2005). Chein Br. 26-29.

2. DEA improperly deviated from its "consistent practice of cooperating with physician registrants" for export registration by failing to communicate with him while his applications were pending and by not providing sufficient guidance during the application process. *Id.* at 29-33.

3. DEA improperly withheld documents from Chein and the ALJ by improperly invoking a law enforcement privilege. *Id.* at 34-35.

4. The DA erroneously concluded that Chein had imported controlled substances from a Mexican pharmacy despite evidence that the delivery was routed through a San Diego warehouse. *Id.* at 33-38.

5. The DA erred in holding Chein liable for violations of the Controlled Substances Act committed by other DEA registrants working at PSLEI. *Id.* at 39-41.

6. The DA incorrectly found that Chein violated the recordkeeping requirements of 21 U.S.C. § 827(b)(2)(B). *Id.* at 41-45.

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objections on the briefs and at oral argument and conclude that only the first merits discussion. In *Morall v. DEA*, 412 F.3d 165 (D.C. Cir. 2005), we vacated DEA's revocation of a physician's registration because DEA had "consistently declined" "to revoke the registration of any other physician in a comparable context, or even under significantly more troubling circumstances" and because DEA offered "no explanation" for the departure from its precedent. *Id.* at 181.[12] We first explained that under the

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7. The DA improperly applied the "public interest" tests prescribed in 21 U.S.C. § 823(a) and (f) by giving insufficient weight to factors favorable to Chein. *Id.* at 45-52.

8. DEA violated due process by submitting evidence it had agreed not to submit and by offering the testimony of a substitute witness at the ALJ hearing. *Id.* at 52-56.

9. The DA erred in finding that Chein's shipments of controlled substances to overseas patients constituted a "diversion" of the substances "within the meaning of the CSA." *Id.* at 56-59.

[12] The DA's decision to revoke Morall's DEA registration was based "solely on . . . her alleged lying to investigators" and "her record-keeping failures." *Morall,* 412 F.3d at 180. Regarding the DA's finding that Morall had lied to investigators, we found that the decision could "not withstand review because the [DA] entirely ignored relevant evidence" of Morall's truthfulness, including testimony "that the ALJ credited" without providing "any reason for rejecting the ALJ's decision to credit Dr. Morall's account." *Id.* at 178 (citing, *inter alia, El Rio Santa Cruz Neighborhood Health Ctr., Inc., v. United States Dep't of Health & Human Servs.,* 396 F.3d 1265, 1278 (D.C. Cir. 2005)) (emphases omitted). Moreover, the record-keeping failures the DA believed warranted revocation "occurred during a relatively brief time period" when Morall was struggling with several personal reversals. *Id.* at 168, 183. Morall had also recently split from her

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Administrative Procedure Act, 5 U.S.C. § 706(2)(A), the DA's choice of sanction is entitled to substantial deference and will be set aside only if her decision is "'arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law.'" *Id.* at 177 (quoting *Tourus Records, Inc. v. DEA,* 259 F.3d 731, 736 (D.C. Cir. 2001) (quoting 5 U.S.C. § 706(2)(A))). Ordinarily, the "mere unevenness in the application of [a] sanction [will] not render its application in a particular case 'unwarranted in law.'" *Id.* at 183 (quoting *Butz v. Glover Livestock Comm'n Co.,* 411 U.S. 182, 188 (1973)) (first alteration in *Morall*). If the revocation represents a "flagrant departure from DEA policy and practice," however, and if the departure is "not only unexplained, but entirely unrecognized in the [DA's] decision, the agency's sanction [cannot] withstand abuse of discretion review." *Id.* at 183.

Addressing *Morall*'s first factor, we believe Chein has failed to demonstrate that DEA has a *consistent* policy of allowing a practitioner to retain his registration under similar circumstances. The numerous

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former business partner, been evicted from her clinic for nonpayment of rent and had not been able to hire support staff. *Id.* When confronted with her record-keeping violations, Morall acknowledged her errors and "readily agreed to take classes to improve her record keeping." *Id.* at 183. We noted that "[n]owhere in its decision, in its brief to the court, or during the oral argument, did DEA identify a single case in which a physician's registration was revoked under analogous circumstances." *Id.* at 181.

cases in which Chein claims DEA has allowed more egregious violators to retain their registrations are easily distinguishable from his.[13] In each of the cases,

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[13] *See, e.g.*, Theodore Neujahr, D.V.M.; Continuation of Registration, 65 Fed. Reg. 5680 (Feb. 4, 2000) (no revocation of veterinarian who kept controlled substances in unlocked drawer at unregistered location; "used his privileges as a DEA registrant to obtain controlled substances to support his chemical dependency"; and "materially falsified his . . . renewal applications"); Karen A. Kruger, M.D.; Grant of Restricted Registration, 69 Fed. Reg. 7016 (Feb. 12, 2004) (no revocation of physician who "unlawfully issued prescriptions [for] approximately 5,500 dosage units of . . . controlled substance[s]" and used falsified prescriptions to support her drug addiction); Jeffrey Martin Ford, D.D.S.; Grant of Restricted Registration, 68 Fed. Reg. 10,750 (Mar. 6, 2003) (no revocation of dentist who abused marijuana, LSD, mescaline and cocaine and had been convicted of drug offenses several years earlier); Wesley G. Harline, M.D.; Continuation of Registration With Restrictions, 65 Fed. Reg. 5665 (Feb. 4, 2000) (no revocation of physician who prescribed medication in violation of state law and "wr[ote] incomplete prescriptions"); Paul W. Saxton, Continuation of Registration, 64 Fed. Reg. 25,073 (May 10, 1999) (no revocation of physician who "prescribed large quantities of controlled substances to individuals who he knew or should have known abused the drugs"; illegally prescribed anabolic steroids to family members and could not "account for large quantities of drugs"); Donald P. Tecca, M.D.; Continuation of Registration With Restrictions, 62 Fed. Reg. 12,842 (Mar. 18, 1997) (no revocation of physician who eight times prescribed anabolic steroids "for no legitimate medical reason" and prescribed controlled substances to undercover agent with alleged drug problem); Mary Thomson, M.D.; Continuation of Registration With Restrictions, 65 Fed. Reg. 75,969 (Dec. 5, 2000) (no revocation of physician who abused opiates and obtained controlled substances by misrepresentation); Barry H. Brooks, M.D.; Continuation of Registration, 66 Fed. Reg. 18,305 (Apr. 6, 2001) (no revocation of physician whose state medical license was suspended and who was convicted of

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the DA, using the public interest standard, imposed a sanction less than revocation primarily because the practitioner had corrected the prohibited practices, accepted responsibility for his or her conduct, cooperated fully with DEA and, where applicable, sought treatment for drug or alcohol addiction underlying the violation.[14] Not so here. Chein cannot credibly

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illegally prescribing Dilaudid for treatment of heroin addiction); Vincent J. Scolaro, D.O.; Grant of Restricted Registration, 67 Fed. Reg. 42,060 (Jun. 20, 2002) (no revocation of physician who abused controlled substances, lacked required records and had criminal conviction).

[14] *See, e.g.,* Neujahr, 65 Fed. Reg. at 5682 ("The [DA] finds it noteworthy that Respondent first sought treatment for his chemical dependency on his own and not at the direction of [DEA]."); Kreuger, 69 Fed. Reg. at 7017-18 ("The [DA] finds significant the Respondent's ready willingness to cooperate with law enforcement authorities . . . [and] to seek treatment for her drug abuse."); Ford, 68 Fed. Reg. at 10,753 ("Respondent beg[a]n attending drug rehabilitation following his . . . arrest, and has not abused controlled substances [during the intervening twelve years]."); Harline, 65 Fed. Reg. at 5672 ("Respondent has taken remedial steps to ensure that he practices in compliance with the law."); Saxton, 64 Fed. Reg. at 25,073 ("[Respondent] ceased such prescribing *immediately* upon learning that it was illegal and has not prescribed anabolic steroids for muscle enhancement since." (emphasis added)); Tecca, 62 Fed. Reg. at 12,846 (respondent acknowledged improper prescribing and testified he had since "become more conservative in his prescribing practices."); Thomson, 65 Fed. Reg. at 75,972 ("Respondent effectively has addressed the personal and professional problems that contributed to her drug abuse [and] take[n] affirmative responsibility for her misconduct. . . ."); Brooks, 66 Fed. Reg. at 18,309 ("Respondent has readily admitted fault, has taken responsibility for his past misconduct, and has fully cooperated with and assisted in the investigations concerning his illicit

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claim that he has cooperated with DEA given his continued exporting of controlled substances after he was repeatedly informed that it was illegal to do so, as well as his continued dispensing of controlled substances even after his DEA registration was suspended. Nor has Chein accepted responsibility for his misconduct as evidenced by, *inter alia,* his continued insistence that his dispensing of anabolic steroids to the undercover agents was proper and his providing misleading information to DEA investigators. *See supra* notes 4, 10. Moreover, we note that Chein engaged in a persistent course of misconduct which, at the time of the notice of immediate suspension, spanned at least seven years. *See Morall,* 412 F.3d at 183 (noting "Morall's record-keeping failures occurred during a relatively brief time period").[15] Because

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activities."); Scolaro, 67 Fed. Reg. at 42,066 ("Respondent has succeeded outstandingly in a well established, aggressive rehabilitation program. . . . "); *see also Morall,* 412 F.3d at 183 ("Morall has always acknowledged that her record keeping suffered . . . and she readily agreed to take classes to improve her record keeping.").

[15] In fact, in several instances, DEA has revoked the registrations of physicians involved in comparable behavior. For example, in John W. Copeland, M.D.; Revocation of Registration, 59 Fed. Reg. 46,063, 46,064 (Sept. 6, 1994), the DA revoked the registration of a physician who had prescribed controlled substances (e.g., Ritalin, Valium, Restoril) to drug addicts and anabolic steroids for bodybuilding. In Rose Mary Jacinta Lewis, M.D.; Affirmance of Immediate Suspension, 72 Fed. Reg. 4035, 4038, 4041 (Jan. 29, 2007), the DA revoked the registration of a physician who provided her DEA registration number to an associate so that he could use the number to order HIV medication to be sent to Nigeria. The physician understood the drugs

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Chein has failed to demonstrate that his revocation represents a "flagrant departure from DEA policy and practice" in analogous cases, *Morall,* 412 F.3d at 183, we need not reach the question whether DEA adequately explained the departure. *Id.* Accordingly we deny the petition for review.[16]

So ordered.

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were to be shipped overseas although neither she, nor her associate, had an export registration. *Id.*

[16] We note, however, the length of time DEA took to issue a final order in this case. It issued the first order to show cause on November 7, 2001; the DA's final order did not issue until January 19, 2007 – over five years later. *See Wedgewood Vill. Pharmacy v. DEA*, 509 F.3d 541, 546, 547 (D.C. Cir. 2007) (noting with disapproval one-year delay between ALJ hearing and ALJ opinion and one-year delay between ALJ opinion and DA's final decision).

72 Fed. Reg. 6580 (Feb. 12, 2007)

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket Nos. 02-09, 02-43]

Edmund Chein, M.D.; Revocation of Practitioner's Registration, Denial of Application for Exporter's Registration Monday, February 12, 2007

Introduction and Procedural History

This is a consolidated proceeding. On November 7, 2001, the then Administrator of the Drug Enforcement Administration, issued an Order to Show Cause and Notice of Immediate Suspension of the practitioner's Certificate of Registration, AC1643661, issued to Edmund Chein, M.D. (Respondent) of Palm Springs, California. The Notice of Immediate Suspension was based on the Administrator's preliminary conclusion that Respondent's continued registration constituted "an imminent danger to the public health and safety because of the substantial likelihood that [Respondent would] continue exporting and diverting controlled substances." Order to Show Cause and Notice of Immediate Suspension at 6 (2001 OSC). The Order further proposed to revoke Respondent's practitioner's registration and deny any pending applications for renewal of the registration on the ground that Respondent's continued registration would be inconsistent with the public interest. *See id.* at 1; *see also* 21 U.S.C. 823(f) & 824(a)(4).

Subsequently, on May 24, 2002, the Deputy Assistant Administrator, Office of Diversion Control, issued an additional Order to Show Cause (hereinafter 2002 OSC) to Respondent. This Show Cause Order proposed to deny Respondent's pending application for a registration as an exporter on the ground that issuance of a registration would be inconsistent with the public interest. 2002 OSC at 1; *see also* 21 U.S.C. 958(c) &(d); *id.* 823(d).

The 2001 OSC alleged that Respondent had purchased "large amounts of anabolic steroids" from a Mexican pharmacy and "other illegitimate sources" and had distributed these substances to individuals who did not have a legitimate medical need for them. 2001 OSC at 2. The OSC further alleged that on May 28, 1996, Federal agents executed a search warrant at Respondent's medical office and seized several vials of steroids for which there were no records. *Id.* The OSC further alleged that in June 1996, DEA obtained from Henry Schein, Inc., copies of invoices which documented that Respondent had purchased controlled substances on nine different occasions between January 1995 and May 1996. *Id.* at 3. The OSC alleged that Respondent had failed to keep accurate records of the purchase, inventory, and dispensation of controlled substances. *Id.*

The 2001 OSC next alleged that on January 31, 2001, DEA Diversion Investigators (DIs) went to Respondent's Palm Springs medical office, the Palm Springs Life Extension Institute (hereinafter PSLEI), to conduct an administrative inspection. *Id.* The OSC alleged that the invoices documenting the purchases of controlled substances were at an accounting firm and not at the office. *Id.* The 2001 OSC further alleged that "none of [the] required controlled substance records were accessible," because the records were stored in a computer and none of the office personnel then present were capable of retrieving them. *Id.* The OSC thus alleged that Respondent had violated the Controlled Substance Act by failing "to maintain in a readily available condition" initial and biennial inventory records, purchase invoices, and dispensing records. *Id.*

The 2001 OSC further alleged that on February 5, 2001, DEA personnel returned to Respondent's office and obtained an inventory of controlled substances that was dated February 5, 2001, dispensing records for the period July 1, 2000, through February 1, 2001, and invoices for purchases of controlled substances from Barnes Wholesale, Inc., for the period January 1, 1999, through February 4, 2001. *Id.* The OSC also alleged that the dispensing records showed that between July 1, 2000, and February 5, 2001, Respondent dispensed anabolic steroids, a Schedule III controlled substance, and phentermine, a Schedule IV controlled substance, to persons in Korea, Belgium, Indonesia, Canada, Japan, Spain, Germany, Switzerland, Mexico, England, and Hong Kong. *Id.* at 3-4.

More specifically, the OSC alleged that Respondent had made 328 illegal exports comprised of 20 exports of phentermine 30 mg., 58 exports of phentermine 15 mg., 73 exports of testosterone gel 8 mg., 12 exports of testosterone gel 100 mg., 50 exports of testosterone estradiol gel 4 mg, 113 exports of Depo testosterone 200 mg., and two exports of testosterone 50 mg. *Id.* at 4. The OSC alleged that these exports were illegal because Respondent was not registered as an exporter, *see* 21 U.S.C. 957(a), and had failed to file the necessary declarations. *See id.* section 953(e); *see also* 2001 OSC at 4. The OSC also alleged that Respondent had failed to maintain proper records of the exports. *See* 2001 OSC at 4.

The 2001 OSC alleged that upon discovering the exports, a DI contacted Dr. Darryl Garber, an associate of Respondent, who informed the DI that Respondent's clinic had patient records for each recipient of the shipments, that some of the recipients were seen at the clinic and others were seen by video conferencing, and that the controlled substances were shipped by Federal Express. *See id.* The OSC alleged that the DI instructed Dr. Garber that the shipments "violated the Controlled Substances Act and must be stopped immediately," and that the DI subsequently faxed Dr. Garber the applicable provisions of the United States Code. *Id.*

The 2001 OSC next alleged that on August 23, 2001, DEA personnel visited the PSLEI and conducted a management conference with Respondent. *Id.* The OSC alleged that during this meeting, the DI told Respondent that the required records "were not readily retrievable on the date of the inspection[ ] as required" by Federal law and that Respondent acknowledged that he had discussed his non-compliance with Dr. Garber. *Id.* at 5. The OSC alleged that during the conference, Respondent admitted that based on the records provided to DEA in February 2001, he "had at least 150 exporting violations already on record." *Id.* The OSC further alleged that Respondent admitted that he had "continued to export controlled substances" notwithstanding the March 2001 warning that the shipments were illegal, and that he would continue to do so until he "received written instructions from DEA." *Id.* The OSC also alleged that when DEA personnel requested that Respondent produce his controlled substance shipping records, Respondent refused to do so and invoked the Fifth Amendment. *Id.*

The 2001 OSC alleged that on various dates following the August 23rd, 2001 meeting, DEA personnel faxed Respondent the applicable provisions of the United States Code and instructed him that he was not authorized to either export or import controlled substances and "must immediately cease" all such activity. *Id.* Based on the above allegations, the Administrator made the preliminary finding that Respondent was "responsible for the diversion of large quantities of controlled substances in violation of 21 U.S.C. 953, 957 and 958." *Id.* at 6. Concluding that there was a "substantial likelihood that [Respondent would] continue exporting and diverting controlled substances," the Administrator ordered the immediate suspension of Respondent's practitioner's registration. *Id.*

The 2002 OSC, which proposed the denial of Respondent's application for an exporter's registration, repeated many of the above allegations. In addition, the 2002 OSC alleged that on April 27, 2001, Respondent had applied for a registration as an exporter of Schedule III (non-narcotic) and Schedule IV controlled substances and that DEA had received the application on May 7, 2001. 2002 OSC at 2. The OSC alleged that the "application was not accepted for filing" and that Respondent's filing fee had been refunded. *Id.* The OSC also alleged that on December 17, 2001, DEA received from Respondent an undated application for a registration to export controlled substances in Schedule III (non-narcotic) and Schedule IV. *See id.* at 3.

The 2002 OSC further alleged that on March 13, 2002, DEA DIs executed an administrative inspection warrant at the PSLEI. *See id.* at 3. The OSC alleged that during the inspection, the DIs seized samples of controlled substances for analysis and obtained copies of invoices, inventories, dispensing logs and patient records. *Id.* The OSC alleged that these records showed that notwithstanding the previous DEA warnings that his exports were illegal, Respondent had "continued to dispense controlled substances * * * to overseas patients until November 14, 2001," the date he was served with the Notice of Immediate Suspension. *Id.* Finally, the OSC alleged that "DEA reviewed the patient records of selected overseas patients and determined that [Respondent had] deviated from the appropriate standard of care for the dispensation of controlled substances." *Id.* The OSC thus concluded that Respondent had "committed acts that would render the approval of [his] pending DEA export application to be inconsistent with the public interest." *Id.* at 3.

Respondent timely requested a hearing on the allegations of each Show Cause Order; the cases were assigned to Administrative Law Judge (ALJ) Gail Randall. The hearing on the issues raised by the 2001 Show Cause Order was initially scheduled to begin on July 9, 2002, in Riverside, California. However, on June 6, 2002, the parties filed a joint motion to consolidate the cases and to continue the hearing. On June 13, 2002, the ALJ granted the motions. ALJ Decision at 2 (ALJ).

The first stage of the hearing was held in Riverside, California, on January 28-31, and February 3-6, 2003. During this portion of the hearing, Respondent objected to DEA's proposed eliciting of testimony of an expert witness, Dr. Robert Zipser, on the issue of whether Respondent's dispensing practices were within the standard of care. Among other things, Respondent asserted that the proposed testimony related to an issue that was outside the subject matter jurisdiction of this Agency. While the ALJ overruled Respondent's objection, she granted Respondent leave to file an interlocutory appeal on the issue. The ALJ further barred Dr. Zipser from testifying about Respondent's dispensing practices until the interlocutory appeal was resolved.

On June 23, 2003, the Acting Administrator denied Respondent's appeal. Thereafter, the second stage of the hearing was held in Arlington, Virginia, on September 9-10, 2003, and the final stage was held in Riverside on December 9 through 11, 2003.

During the hearing, both parties called witnesses and introduced documentary evidence. Following the hearing, both parties submitted proposed findings, conclusion of law, and argument.

On July 28, 2005, the ALJ issued her recommended decision. In that decision, the ALJ recommended that I revoke Respondent's practitioner's registration. ALJ at 82. The ALJ further recommended that I deny Respondent's application for an export registration. *See id.* Neither party filed exceptions.

Thereafter, the ALJ forwarded the record to me for final agency action. On December 29, 2005, Respondent's counsel submitted a letter to me setting forth various "issues for review, exception, appeal and judicial review," Resp. Ltr. at 1, and including as attachments copies of various filings and motions that were previously submitted during the course of this all too lengthy proceeding. To the extent Respondent's letter raises "exceptions" as that term is used in the Administrative Procedure Act, *see* 5 U.S.C. 557(c), it is out of time.[1] *See* 21 CFR 1316.66(a)

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[1] Respondent's letter does not specify which of the ALJ's findings of fact and conclusions of law he is excepting to. Nor

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(requiring filing of exceptions "[w]ithin twenty days after the date upon which a party is served a copy of the report of the" ALJ).

Having carefully considered the record as a whole, I hereby issue this final order. For the reasons set forth below, I concur with the ALJ's conclusion that Respondent's continued registration as a practitioner would be inconsistent with the public interest and therefore adopt the ALJ's recommendation that Respondent's registration should be revoked. I further concur with the ALJ's conclusion that granting Respondent's application for registration as an exporter would be inconsistent with the public interest and therefore adopt the ALJ's recommendation that the application be denied. I make the following findings.

Findings of Fact

Respondent is a medical doctor and holds a license with the Medical Board of California. Gov. Exh. 3, at 1. Respondent graduated in 1980 from the American University of the Caribbean School of Medicine and also holds a law degree. *Id.*; *see also* ALJ at 5. Respondent practices anti-aging medicine and is the owner of the Palm Springs Life Extension Institute (PSLEI). ALJ at 5-6.

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does it provide "a statement of supporting reasons for such exceptions, together with evidence of record * * * and citations of authorities relied upon." 21 CFR 1316.66(a).

Respondent has developed a treatment protocol called Total Hormone Replacement Therapy and obtained various patents for it.[2] *See generally* Resp. Exh. 1017. Respondent's practice involves using blood tests to determine the levels of various hormones in a person and prescribing various substances including hormones such as Human Growth Hormone and Estrogen to a patient based on the level of these hormones found in a healthy young adult. *See generally id.* Most significantly, as part of his treatment protocol, Respondent frequently prescribed and dispensed several controlled substances including testosterone in various formulations, a Schedule III anabolic steroid (*see* 21 CFR 1308.13(f)), and phentermine, a Schedule IV stimulant. *See* 21 CFR 1308.14(e). Respondent used the term "adrenal extract" for phentermine. *See* Gov. Exh. 117; Gov. Exh. 135.

Respondent holds a DEA Certificate of Registration as a practitioner, No. AC1643661, which authorizes him to dispense controlled substances in Schedules II, II-N, III, III-N, IV and V. Gov. Exh. 2. Respondent's registered location is 2825 Tahquitz Canyon Building A, Palm Springs, CA, 92262. *Id.*

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[2] To obtain a U.S. patent, Respondent was not required to demonstrate the safety or effectiveness of his protocol. *See* Gov. Exh. 138, at 4 (Manual of Patent Examining Procedure § 2107.03).

The First Investigation

Respondent first came to the attention of DEA in 1994, when a U.S. Food and Drug Administration (FDA) Special Agent (SA) contacted Robert Brasich, a Diversion Investigator assigned to the San Diego Field Division, seeking a person to assist in an undercover investigation of Respondent. Tr. 112. The FDA SA asked the DI whether he knew of any DEA SA who could pose as body builder and perform an undercover visit with Respondent. *Id.* at 118. The FDA SA told the DI that he had personally conducted an undercover meeting during which he told Respondent that he played rugby and wanted to increase his strength and endurance. *Id.* at 120. At the end of the visit, Respondent's staff gave the FDA SA human growth hormone (HGH) and the FDA SA subsequently received shipments of HGH on several occasions.[3] *Id.*; *see also* Gov. Exh. 35, at 23.

On October 17, 1994, another FDA SA also performed an undercover visit with Respondent. *Id.* at 24. This SA told Respondent that he had an injured disc, that he lifted weights, and that he wanted to increase his muscle mass, and that he had taken steroids previously "but wanted a safer alternative." *Id.* at 25; *see also* Tr. at 121. According to an affidavit filed to obtain a search warrant, Respondent told the SA that "the problem with anabolic steroids in the past was their use without medical supervision, but they weren't bad if administered by a doctor." Gov. Ex. 35, at 25. At the end of the consultation, Respondent gave the SA prescriptions for various items including testosterone gel, a Schedule III controlled substance. *Id.* at 26. While Respondent obtained a blood sample, he issued the prescription for testosterone without obtaining the results. *Id.* at 26; *see also* Tr. at 149.

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[3] HGH is not a controlled substance. The facts surrounding this visit are related solely to provide context.

On March 17, 1995, a Customs SA performed an undercover visit with Respondent. The Customs SA told Respondent that he was a competitive powerlifter and used anadrol, an anabolic steroid, but that he wanted HGH because he had lost competitions "to guys who [were] 'on the juice.'" Gov. Exh. 35, at 32. During the visit, Respondent told the SA that "[a]fter 1990, the whole body-building industry had switched to natural testosterone, and the 'new power lifting people use testosterone and HGH.'" *Id.* Respondent also told the SA that the "most effective treatment for [his] goal would involve both [HGH] and natural testosterone administered through the skin by means of a patch or gel." *Id.* Respondent further told the SA that the "testosterone would not show up in drug testing at competitions if [he] followed [Respondent's] instructions." *Id.* at 33. While Respondent drew blood from the SA during this visit to determine his testosterone and HGH levels, the results were not available by the end of the consultation. *Id.* at 33-34; *see also* Tr. at 149. Respondent nonetheless gave the SA prescriptions for various items including testosterone. *Id.* at 34.

Moreover, Respondent gave the SA a letter entitled "testosterone Replacement Therapy," which stated that the SA "had been diagnosed with hypogonadism for which testosterone replacement therapy was required." *Id.* The letter further stated that all the testosterone prescriptions and refills would be filled by a pharmacy in Fairfax, Virginia, and that Respondent would send the SA's prescription directly to the pharmacy. *Id.* at 34-35.

Finally, on July 20, 1995, a DEA SA conducted an undercover visit with Respondent. *Id.* The SA told Respondent that he was a powerlifter and was training to make the Olympic team. *Id.* Respondent told the SA that because he "had not done a lot of steroids in the past," his "testosterone would be low which would provide a justification for prescribing testosterone." *Id.* at 36. Respondent drew blood from the SA, *id.* at 37, and told him that "if the results came back low" he would also ship him HGH. *Id.* at 36. Respondent also gave the SA "a letter entitled 'testosterone Replacement Therapy.'" *Id.* at 37. The letter "was identical in substance to the letter given to" the Customs SA during the third undercover visit. *Id.* Thereafter, the same Fairfax, Virginia pharmacy mentioned in the letter Respondent gave the Customs SA sent 50 mg. of testosterone gel to the DEA SA. *Id.* at 38.

Subsequently, on May 23, 1996, the FDA SA obtained a search warrant for the PSLEI. *Id.* at 2. Two DEA DIs participated in the execution of the search. Tr. at 130. During the search, controlled substances, which included testosterone gel, testosterone cypionate and nandrolone decanoate, were found on the premises. *Id.* at 132; Gov. Exh. 35, at 71. Moreover, while the CSA requires a registrant to maintain at his registered location purchase records, an inventory, and a dispensing log, *see* 21 CFR 1304.03 & 1304.04, no such records were found on the premises during the search. Tr. at 134. The investigation also determined that on numerous occasions between January 1, 1995, and June 3, 1996, Respondent had purchased controlled substances including diazepam (Schedule IV) and various anabolic steroids including deca-durabolin, nandrolone decanoate, and testosterone cypionate from Henry Schein, Inc. *See* Tr. 135, Gov. Exh. 36.

The Second Investigation

On June 29, 1998, the Medical Board of California initiated proceedings against Respondent which resulted in an administrative hearing before a state ALJ. Govt. Exh. 3, at 1; Gov. Exh. 125. In a decision dated December 27, 1999, the state ALJ issued a decision which proposed the revocation of Respondent's state medical license. Gov. Exh. 4, at 67. On January 19, 2000, the Medical Board's Division of Medical Quality entered an order adopting the ALJ's decision with an effective date of February 18, 2000.[4] *See id.* at 32.

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[4] Respondent, however, sought judicial review in the California state courts. On September 26, 2000, the Superior Court granted Respondent's petition in part and ordered the Medical Board to set aside its decision revoking Respondent's license and remanded the case for further proceedings; on November 9, 2000, a judgment to this effect was entered. *See* Gov. Exh. 4, at 25-26. On January 4, 2001, the Medical Board subsequently vacated and set aside its decision. *Id.* at 1.

Subsequently, on August 15, 2002, the Medical Board filed an additional accusation against Respondent which alleged thirteen grounds for discipline including incompetence, prescribing without medical indication, "obtaining controlled substances by deceit, misrepresentation and subterfuge," "dispensing controlled substances without proper privileges," and failing to maintain adequate controlled substance records. Govt. Exh. 124, at 18; *see also id.* at 10-11. This matter was still pending at the time the record closed. *See* ALJ at 15.

Pursuant to 5 U.S.C. 556(e), I take official notice of the fact that on September 22, 2005, Respondent entered into a Stipulation Settlement and Disciplinary Order with the State of California, which became effective on March 16, 2006. *See In the Matter of the Accusation Against: Edmund Chein, M.D.*, File No. 19-2000-107723, Decision at 1, Stipulated Settlement and Disciplinary Order at 14. I further note language in the stipulation asserting that it "is intended to resolve" not only California's disciplinary action but also "any disciplinary action taken by another state or the federal government based on the conduct alleged in * * * In the Matter of Edmund Chein, M.D., Docket No. 02-9 and 02-43 pending before the United States Drug Enforcement Administration." Stipulated Settlement at 2-3. In accordance with the Administrative Procedure Act, publication of this order will be withheld for a fifteen day period in order to provide Respondent with "an opportunity to show the contrary." 5 U.S.C. 556(e).

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On July 20, 2000, Respondent submitted an application to renew his practitioner's registration (DEA From [sic] 224a). Gov. Exh. 1, at 1. His California license having been revoked, Respondent gave the address of his proposed registered location as XXX XXXXX XXXX, XXXXX XXX, Salt Lake City, UT 84111. *Id.* at 2; Gov. Exh. 18, at 1. Moreover, in response to a question on the application, Respondent indicated that his California license had been revoked but that his Utah license was "not affected." *See* Gov. Exh. 1, at 2.[5] Because Respondent had indicated that California had revoked his license, the application was not automatically renewed but forwarded to the DEA Salt Lake City office and then to the DEA Riverside, California field office, for further investigation, where it was assigned to Diversion Investigator Doris DeSantis. Tr. at 216-17.

No longer holding a valid California medical license, on or about February 16, 2000, Respondent sold the PSLEI to his sister Connie Chein, a board certified physician who practices obstetrics and gynecology in Beverly Hills, California. ALJ at 6-7.

The ALJ also found that on June 30, 1995, the Medical Board placed Respondent on probation for a three year period for false advertising and failing to obtain a fictitious name permit. *See* ALJ at 12-13.

[5] On March 5, 2001, DEA received from Respondent a letter which requested a modification of his registration back to 2825 Tahquitz Canyon Way, Building A, Palm Springs, CA, 92262, because he had "since * * * regained [his] California Medical License." Gov. Exh. 18.

Dr. Connie Chein testified that she purchased PSLEI because under California law, "you have to be a licensed physician to own a medical facility." Tr. 1087. The ALJ found that during this period, PSLEI was operated by Dr. Darryl Garber, an associate of Respondent. *See* ALJ at 13 (citing Tr. 1050). On or about December 20, 2000 (and following the Superior Court's granting of judgment setting aside the State Board's revocation order), Dr. Connie Chein sold the PSLEI back to Respondent. *Id.* at 7.[6]

Dr. Connie Chein holds a DEA Certificate of Registration as a practitioner, No. AC7093292, with a registered location in Beverly Hills, California. Gov. Exh. 43, at 8. On various occasions, PSLEI ordered controlled substances using Dr. Connie Chein's DEA registration. *See* Gov. Exh. 43, at 2-6; Gov. Exh. 17 (invoices ordering phentermine from Barnes Wholesale); Gov. Exh. 44(d), 44(g), 44(l), & 45(a) (invoices for testosterone ordered from Amend Drug & Chemical Co., Inc.); Gov. Exh. 31 (Letter dated Dec. 17, 2001, from Marshall Gilbert, Administrator, PSLEI, to Spectrum Chemicals) ("Dr. Connie Chein is no longer with [PSLEI]. Dr. Darryl Garber is now in charge of ordering all controlled substance[s].").

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[6] Given the circumstances surrounding Respondent's sale of the clinic to his sister and her sale back to him, the transaction may well have been a sham. But the Government did not attempt to prove that it was.

During a December 13, 2001, interview with DEA Diversion Investigators (DIs) at which she was represented by counsel, Dr. Connie Chein stated that she never gave Respondent permission to use her DEA registration to order controlled substances for PSLEI. Gov. Exh. 28, at 15. Moreover, Dr, Connie Chein stated that she never received controlled substances at her Beverly Hills registered location which were intended for PSLEI and was unaware of the fact that someone at PSLEI was using her DEA registration to order controlled substances for the clinic. *Id.* at 15-17, 19.

At the hearing, Dr. Connie Chein testified that she never treated patients at PSLEI. Tr. 1092. When asked, however, as to whether she had ever prescribed or dispensed controlled substances for patients of the PSLEI, Dr. Connie Chein asserted the Fifth Amendment privilege against self-incrimination. *Id.* at 1093. Moreover, when asked whether she had ever ordered controlled substances for PSLEI, Dr. Connie Chein again invoked her Fifth Amendment privilege. *Id.* at 1094. Dr. Connie Chein also asserted her Fifth Amendment privilege when the Government attempted to question her regarding various invoices and purchase orders which used her DEA number and related documents. Tr. 1111-12; 1116-19; 1121-36.

The Government contends that notwithstanding Connie Chein's ownership, Respondent remained in charge of the Palm Springs Clinic during the period in which his state license was revoked. There is substantial evidence in the record that supports this contention.

For example, on February 27, 2000, Respondent wrote an "Interoffice Memo" directing the Oral/Growth Hormone Department to not "ship any bottle to Japan, if the bottles do not appear clean to you, because the Japanese custom is extremely clean." Gov. Exh. 136, at 14. The memo further instructed that "testosterone tubes frequently have adhesive that appears black to them" and that "it must be removed * * * before it can be shipped out." *Id.* The memo directed clinic employees to "sign that you have read this letter/memo, and return it to my desk. From, Dr. Edmund Chein." *Id.* The memo also stated that if there were "any questions about the quality or the product, you must let Charlie or Vanessa or me know, before" shipping the products. *Id.* Respondent's secretary, who worked at PSLEI's Palm Springs, Cal. clinic, was Vanessa Koloen. Tr. 1331-36

Thereafter, in an Interoffice Memo dated February 29, 2000, Respondent directed the Growth Hormone Department to ship phentermine to a patient in Japan. *See* Gov. 105, at 36. Specifically, the Memo reads: "Mandy, please ship one (1) bottle of phentermine to Ms. [K. H.] immediately.[7] However, ship the oral hormone, phentermine to Yamamoto Medical Clinic, instead of to her home address." *Id.* Other documents in the record establish that Ms. Mandy Boriski was involved in the filling of orders for Respondent's patients and worked out of the Palm Springs, Cal. clinic. *See* Gov. Ex. 96, at 32, 33, 34, 36, 38.

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[7] To protect patient privacy, patients will be referred to by their initials.

One of these documents is a July 14, 2000 memo from Ms. Boriski to Dr. S.K., a German patient. The memo, which used the clinic's Palm Springs, California address states: "I have received your fax re: the order with the pharmacy. *I am awaiting approval from Dr. Chein* for me to send the prescriptions you requested. I apologize for the delay but I am unable to send anything *without his approval*." Gov. Exh. 96, at 32 (emphasis added).

The record also contains a December 13, 2000 e-mail from Bob Jones, a consultant and spokeperson [sic] for PSLEI to various employees of the Palms [sic] Springs location, which discussed missing testosterone shipments to a German citizen, R.D. The e-mail, which was copied to Respondent and his Secretary Vanessa Koloen, states: "Per Dr. Chein please send duplicates of their last shipments of these items today." Gx. 107, at 23. As these various documents indicate, Respondent was still the boss during the period in which his sister putatively owned the clinic and continued to direct the clinic's employees in the handling of controlled substances.

It is acknowledged that during this period, Respondent sometimes used letterhead that referred to PSLEI's "International Division" and gave an address in Salt Lake City, Utah, and typically used a prescription form that included his Utah medical license number. But even if Respondent actually maintained a medical practice in Utah, his doing so does not exclude a finding that during this period, Respondent continued to direct his employees regarding the distribution of drugs from the clinic's Palm Springs, California location.[8]

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[8] Other documents support the conclusion that Respondent remained active in practicing medicine out of the Palm Springs, California location. On May 22, 2000, Respondent sent a letter by fax to Dr. S.K. Gov. Exh. 96, at 41. In this letter, Respondent advised Dr. S.K. that her mother was "not too old for the program" and that "[s]he may want to be on the silver program, which is the basic hormone-balancing program without the growth hormone." *Id.* Significantly, while this document was not written on PSLEI's letterhead, Respondent used the clinic's Palm Springs fax number.

The record also contains correspondence written by Respondent during this period on letterhead using the clinic's Palm Springs, Ca. address. *See* Gov. Exh. 94, at 8. In an October 6, 2000 letter, Respondent rendered medical advice to a Japanese clinic regarding patient M.I. *See id.* Subsequently, on October 13, 2000, Dr. Chein wrote this patient on PSLEI's Palm Springs, CA letterhead advising that there was a dispute between himself and the doctors at the Aoyama Medical Clinic. *Id.* at 6.

Thereafter, on December 5, 2000, Respondent wrote a letter on the clinic's Palm Springs, Ca. letterhead notifying the patient that "starting from 9th November 2000 the relation between Aoyama Clinic and my Institute (Palm Springs Life Extension Institute, CA, U.S.A.) has come to an end." *Id.* at 5 (emphasis added). Respondent thus represented to others that he was the owner of the clinic during the period in which his sister putatively owned it. Moreover, the statement shows Respondent's

(Continued on following page)

Indeed, in the case of patient N.K., a Japanese citizen, Respondent wrote a letter (dated October 11, 2000) to the patient on Palm Springs, California letterhead discussing the results of a "hormonal screening panel test"; the letter also recommended that the patient take testosterone gel and Adrenal Extract (phentermine). Gov. Exh. 93, at 6. Respondent also prepared a form on "Palm Spring [sic] Life Extension Institute, Utah" letterhead, which prescribed numerous products including testosterone gel and phentermine (Adrenal Extract). *Id.* at 13. Both documents were faxed on October 19, 2000, and bear initials showing that the same person faxed both documents. *Compare id.* at 6, *with id.* at 13. Subsequently, on November 22, 2000, the Palm Springs, California location dispensed testosterone gel to this patient. *See* Gov. Exh. 15, at 20.

I further note that notwithstanding her putative ownership of the clinic, Respondent's sister could not provide DEA investigators with copies of the documents that transferred ownership. *See* ALJ at 20 [¶ 74]. Furthermore, Respondent's sister told DEA investigators that she had been out to the clinic's Palm Springs location once in five years. *See id.* The ALJ also found that Dr. Garber operated the clinic during this period. *Id.* at 13 [¶ 52]. But during this period, Dr. Garber's registered location was at his

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continued involvement in the business affairs of the Palm Springs clinic.

residence and not at the clinic. *Id.* at 21 [¶ 76]. In any event, the ALJ's finding that Dr. Garber operated the clinic does not preclude the additional finding that Respondent continued to exercise control over the Palm Spring [sic] location's handling of controlled substances during the period in which his sister owned the clinic.

The ALJ found that Respondent dispensed controlled substance [sic] from PSLEI while his California medical license was revoked. *See* ALJ at 13-14, ¶ 52 (citing Tr. 827-29; Gov. Exh. 105, at 36, 45-46). I adopt this finding. As found above, a February 29, 2000 memo from Respondent directed an employee in the "Growth Hormone Department" to "ship one (1) bottle of phentermine to [Ms. K. H., a Japanese patient] immediately." Gov. Exh. 105, at 36. *See also id.* at 45-46 (Feb. 29, 2000 letter from Respondent to Ms. K. H.; "due to your twenty pound weight gain, I will add phentermine adrenal hormone immediately."). Moreover, as explained above, the evidence shows that Respondent dispensed testosterone Gel to patient N.K. from the Palm Springs location while his California medical license was revoked.

The ALJ also found that "on August 11, 2000, the Respondent, without a DEA registration entitling him to so act, sent controlled substances from PSLEI, International Division, in Salt Lake City, Utah, to Japan." *See* ALJ at 14, ¶ 53 (citing Gov. Exh. 105, at 39-42). I do not adopt this finding. While the documents which the ALJ relied on establish that HGH and "oral hormones" were to be shipped, they do not establish that the "oral hormones" included a controlled substance.

The ALJ also made a finding that "[s]ome of the shipments sent from PSLEI were mislabled [sic] to avoid disclosing that the package contained controlled substances." ALJ 57, ¶ 192. Relatedly, the Government argues that various documents "reflect[] PSLEI's willingness to fraudulently misidentify shipments of drugs to mislead customs officials." Govt. Br. at 50, ¶ 98.

The document cited by the ALJ does suggest that testosterone gel was labeled as "'a Skin Cream' and as a 'gift' for Customs purpose." Gov. Ex. 107, at 21. A subsequent e-mail, dated December 13, 2000, which was copied to Respondent, indicated that the substances had not been received and directed the Palm Springs staff to send a new shipment that day. *Id.* at 23. The e-mail further included "guidelines for shipping to Germany" from the patient's secretary, which stated that the goods should be declared as a "sample" with a value of "$5.00." *Id.* But while the invoice that accompanied the shipment declared its value at $5.00, it also clearly described the goods as "testosterone." *Id.* at 20. This document thus does not support the ALJ's finding.

The Government also points to a September 8, 2000 fax from Ms. Boriski to a Belgian citizen informing him that his order for melatonin had been shipped and "labeled as [a] Dietary supplement * * * per your request. I hope this does eliminate any delay with customs." Gov. Ex. 91, at 22. However, melatonin is not a controlled substance and it is arguably accurate to describe it as a "dietary supplement." Moreover, even if it was improper to declare it as a dietary supplement, this document does not establish that Respondent was aware of this practice, and a single document does not prove that it was the clinic's policy or practice to falsify customs declarations.

Finally, the record contains a letter from Dr. S.K. ordering estradiol/testosterone creme and suggesting that "it might be [declared as] a cosmetic product." Gov. Exh. 96, at 45a. The Government, however, produced no evidence showing that the clinic did, in fact, mislabel the shipment. Accordingly, the ALJ's finding is not supported by substantial evidence. *See NLRB* v. *Columbian Enameling & Stamping Co.*, 306 U.S. 292, 300 (1939) ("Substantial evidence is more than a scintilla, and must do more than create a suspicion of the existence of the fact to be established.").

The DEA On-Site Inspections and Their Aftermath

As stated above, because Respondent's state license had been revoked, DI DeSantis was assigned to conduct an investigation regarding his renewal application. On January 31, 2001, the DI went to the PSLEI in Palm Springs to interview Respondent and inspect his recordkeeping. Tr. 263; Gov. Exh. 5. Respondent was not present. Tr. 264. The DI met with

Dr. Darryl Garber and presented him with a Notice of Inspection. Gov. Exh. 5.

The DI asked to see various records including invoices for the purchase of controlled substances, inventories, and dispensing logs. Tr. 268-69. Dr. Garber told the DI that he could not provide the records because PSLEI had a new computer system and no one was present who could access the records. *Id.* at 269. One of PSLEI's employees told the DI that the invoices were not on-site but rather were at the office of its accountant. *Id.* at 273. The only records the DI received were two purchase orders but these had been generated by the PSLEI and were not the invoices provided by the distributor. *See* Gov. Exh.6; Tr. 274-75. The purchase orders did, however, establish that the PSLEI had recently bought phentermine. *See* Gov. Exh.6.

The DI told Dr. Garber that the clinic was in violation of the CSA's implementing regulations because the invoices were required to be kept on-site. Tr. 274-76. The DI also informed Dr. Garber that the clinic was in violation because the records were not readily retrievable for inspection and copying. *Id.* at 274.

On February 5, 2001, the DI returned to the PSLEI to obtain the records that the clinic was required to maintain. Once again, Respondent was not present. *Id.* at 279. The DI again met with Dr. Garber and asked for the records. *Id.* Dr. Garber asked the DI to sit in the office while he retrieved the records.

Id. The DI waited two to three hours while Dr. Garber printed out the records. *Id.* at 280.

Dr. Garber provided the DI with a one page inventory report which was dated February 5, 2001. *See* Gov. Exh. 8. Dr. Garber also provided the DI with four invoices for phentermine. Tr. 331-33; Gov. Exh. 17(a)-17(d). Although the DI had requested the invoices for all controlled substances purchased by the clinic, no invoices for the purchase of testosterone were provided. Tr. 334.

Dr. Garber also provided the DI with a dispensing log for various controlled substances including testosterone gel, testosterone estradiol gel, Subligual [sic] testosterone, testosterone, and depo testosterone. *See* Gov. Exhs. 9-16; Tr. 284. Most of the dispensing logs, however, only covered the period from July 1, 2000, through February 5, 2001.[9] *See* Gov. Exhs. 9-16. Moreover, none of the logs indicated the name of the physician who had authorized each dispensing. *See id.* The logs also included the names of numerous patients who resided in foreign countries including Belgium, France, Germany, Great Britain, Spain, Switzerland, China (Hong Kong), Indonesia, Japan, South Korea, and Canada. *See* Gov. Exhs.10, 11, 12,

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[9] The dispensing log for phentermine 15 mg. covered the period from July 26, 1999, through February 1, 2001. *See* Gov. Exh. 10. This log, however, had no entries before August 22, 2000. *See id.* The dispensing log for Depo testosterone covered the period July 1, 2000, through February 1, 2001. *See* Gov. Exh. 16.

15, & 16. The Government subsequently compiled from these records a separate document which listed each dispensing. *See* Gov. Exh. 46. According to this document, the dispensing logs showed that Respondent's clinic exported controlled substances 317 times during the period from July 1, 2000, through February 5, 2001.[9] [sic] *See id.*; *see also* ALJ at 57, ¶ 191. Neither Respondent nor Dr. Garber had an export registration as required under 21 U.S.C. 957 & 958.[10]

On March 9, 2001, DI DeSantis contacted Dr. Garber by telephone and told him that PSLEI must stop exporting controlled substances. Tr. 1245. The DI also faxed to Dr. Garber various provisions of Federal law pertaining to the exporting of controlled substances including 21 U.S.C. 953 & 960. *Id.*; *see also* Gov. Exh. 19. On the same day, Vanessa Koloen, a PSLEI employee, faxed to the DI copies of various documents including purchase orders and invoices related to the clinic's purchase of testosterone. *See* Gov. Exh. 20. The earliest documents were, however, dated November 20 & 21, 2000, *see* Gov. Exhs. 20(J) & 20(K), and the dispensing records indicated that testosterone had been dispensed before these dates. *See, e.g.*, Gov. Exh. 15, at 21-26. Two other documents provided by PSLEI used Dr. Garber's residence as the billing and shipping address. *See* Gov. Exhs. 20(F) & 20(G). The remaining documents were for purchases that occurred in mid to late February 2001, following the DI's second visit. *See* Gov. Exhs. 20(a), 20(b), 20(c), 20(d), 20(e).

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[10] While Dr. Garber held a DEA practitioner's registration, at the time of the January 31 and February 5, 2001 visits, his registered location was his residence in Rancho Mirage, California. *See* ALJ at 21, ¶ 76. Dr. Garber did not change his registered location to the PSLEI until February 12, 2001, after the two visits. *See id.*

Subsequently, on April 27, 2001, Respondent applied for a registration to export Schedule III Non-Narcotic and Schedule IV controlled substances. *See* Gov. Exh. 48, at 3-4. According to a date stamp, the application was received at DEA in May 7, 2001, and Respondent's credit card was charged on May 15, 2001. *See id.* at 3. The application, however, was never processed and the application fee was refunded through a credit to Respondent's credit card. Tr. 2092-94 The application bears the notation "Already Have DEA#." Gov. Exh. 48, at 3. The application was not returned to Respondent, and no one at DEA ever notified him that the application had been rejected. *See* Gov. Exh. 34 & 39; *see also* Resp. Proposed Findings at 12 (¶ 94). In December 2001, Respondent submitted a second application for registration as an Exporter. *See* Gov. Exh. 48 at 7-8.

On August 23, 2001, DI DeSantis (accompanied by another DI) returned to PSLEI to conduct a conference with Respondent regarding the violations that had been found during the inspection. Tr. 545-47. The DI told Respondent that the violations included the clinic's lack of readily retrievable records, its lack of a biennial inventory, and its exporting of controlled substances to persons residing in foreign countries without an export registration. *Id.* at 547-48, 559.

During the meeting, Respondent produced the statutes that the DI had faxed to Dr. Garber and acknowledged that he had discussed the violations with Dr. Garber. *Id.* at 548. Respondent admitted that he did not have an exporter's registration and claimed that under either 21 U.S.C. 953(a)(3) or (a)(4) he could export without a registration because he was sending the controlled substances to another doctor, who was legally authorized to handle controlled substances. Tr. 551-55. The DI informed Respondent that he would still need an export permit under 21 U.S.C. 953(a)(5). *Id.* at 554. These provisions, however, address the exportation of narcotic drugs and not the non-narcotic controlled substances (testosterone and phentermine) that Respondent was exporting. Rather, the export of these controlled substances is governed by 21 U.S.C. 953(e), which requires the filing of a declaration and documentary proof that the importation into the destination country is not illegal.[11] Moreover, a registration is required to export

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[11] The record contains letters from the governments of Japan and Taiwan to Respondent's associate (Dr. Garber) establishing the illegality of PSLEI's exportation of phentermine to persons residing in these countries. In a December 11, 2001 letter, the Government of Japan notified Dr. Garber that "[w]ith regard to the medicine containing phentermine, you must not send the medicine to your patient in Japan." Gov. Exh. 38(C) (Tab D) (Letter from Kaoru Misawa, Deputy Director, Compliance and Narcotics Division, Pharmaceutical and Food Safety

(Continued on following page)

both narcotic and non-narcotic controlled substances. *See* 21 U.S.C. 957 & 958.

During the meeting Respondent did not mention that he had applied for an exporter's registration. Moreover, Respondent told the DI that he had continued to export controlled substances notwithstanding her earlier admonition to Dr. Garber to stop. Tr. 557. Respondent further admitted that there had probably been many more violations in the interim but that he would not stop until "he received something in writing from" the DEA. *Id.* at 558.

Bureau, Ministry of Health, Labor, and Welfare of Japan, to Darryl J. Garber). According to this letter, a "patient can import the medicine into Japan if he carries the medicine containing less than 1.125 grams of phentermine by himself when entering into Japan." *Id.* This letter further states that while the Government of Japan did not object to the exportation of testosterone gel to a patient in Japan, the medicine must be "for his personal use and of the amount within one-month['s] consumption." *Id.*

In a January 4, 2002 letter, the Government of Taiwan informed Dr. Garber that "phentermine * * * has been prohibited for use by the Department of Health since December 8, 1980, and is not allowed for importation." Gov. Exh. 38(C) (Tab E) (Letter, Kai-Yuan Tan, M.D., Director-General, Bureau of Medical Affairs, Department of Health, Taiwan, to Darryl J. Garber, M.D.).

The record also contains a letter dated July 26, 2001 from Dr. Garber to Raymond A. Conner, Diversion Group Supervisor in DEA's Riverside, California, office. In this letter, Dr. Garber acknowledged that "[i]n Japan and Korea it is against the law to prescribe Anabolic Steroids * * * and phentermine * * * for the purpose of Anti-Aging Medicine." Gov. Exh. 38(C) (Tab C).

The other DI asked Respondent how he was shipping the controlled substances overseas. *Id.* Respondent refused to answer and invoked his Fifth Amendment privilege against self-incrimination. *Id.* He also told the investigators that "it was up to [DEA] to find out how he was shipping [the controlled substances] overseas." *Id.* at 559.

During the meeting, Respondent provided the DI with several invoices for controlled substances. One of the invoices documented that on March 14, 2001, PSLEI had purchased five kilograms of micronized testosterone from Pharmacia and Upjohn and that the product was shipped to Dr. Garber's residence. *See* Gov. Exh. 21.5, at 2. At the time, Respondent owned PSLEI and Dr. Garber was no longer registered at his residence. *Id.*

Respondent also provided the DI with an invoice from Farmacias Castaneda, a pharmacy located in Tijuana, Mexico. *See* Gov. Exh. 22, Tr. 576. The invoice, which is dated June 26, 2001, indicated that the PSLEI had purchased 120 units of Depo testosterone and 40 units of Decadurabolin, two anabolic steroids and Schedule III controlled substances, from the Tijuana pharmacy. *See* Gov. Exh. 22. The pharmacy did not hold a DEA registration because DEA does not register foreign pharmacies or distributors. Tr. 573-74. Neither Respondent, nor Mr. Romero, the pharmacy's owner, was registered as an importer. *See* ALJ at 60, ¶ 205 (citing Tr. 167 & 970); Gov. Exh. 2.

On August 31, 2001, DI DeSantis sent an additional fax to Respondent which included copies of 21 U.S.C. 823, 952, 953, 954 and 958. The "Comments" portion of the Cover Sheet included the following statement:

> I have attached all the registration requirements. * * * concerning applicants to import or export controlled substances. You are not currently registered with DEA as an exporter/importer (nor do you possess any permits to export issued by the Attorney General), thus you are not authorized to perform either activity. You must immediately cease all [activity] in these areas as previously instructed on 02/13/01 and 8/23/01 by D/I DeSantis.

Gov. Exh. 23, at 1. On September 5, 2001, DeSantis sent an additional fax that included a copy of 21 U.S.C. 957 (Persons required to register), which had been omitted from the previous fax. *See* Gov. Exh. 24.

On November 12, 2001, DI DeSantis along with other DEA personnel, served the first Order to Show Cause and Notice of Immediate Suspension. Tr. 591. Upon her arrival at the PSLEI, the DI was informed that Respondent was out of the country and was not expected to return for possibly two weeks. *Id.* at 592. The DI then met with Dr. Garber and asked for Respondent's DEA Certificate of Registration. *Id.* at 592. Neither Dr. Garber, nor Respondent's secretary, Vanessa Koloen, knew where the certificate was. *Id.* at 593.

The DI also sought to seize the controlled substances on the premises. *Id.* Dr. Garber told the DI that Respondent "had not purchased any controlled substances" and that controlled substances at the clinic were purchased by him. *Id.* at 593-94. Dr. Garber refused to turn over the controlled substances. *Id.*

The DI then requested to see the invoices for controlled substance purchases to verify Dr. Garber's statement. *Id.* at 594. Clinic personnel gave the DI various invoices. *Id*; *see also* Gov. Exh. 45. The first of these invoices documented that on March 26, 2001, PSLEI had purchased two kilograms of testosterone (which was received on March 30, 2001) using Connie Chein's DEA number. *See* Gov. Exh. 45a. The next three invoices documented that on three dates in February and March 2001 (Feb. 16 & 21, Mar. 13, 2001), PSLEI purchased various quantities of testosterone which was shipped to Dr. Garber's residence. *See* Gov. Exh. 45(b), (c), & (d). The first two of these invoices (the Mar. 14 Pharmacia & Upjohn and the Feb. 16 Gallipot) did not have a DEA number. The third invoice (the Feb. 21 Gallipot) used Respondent's DEA number even though the controlled substances were shipped to Dr. Garber's residence. *See* Gov. Exh. 45(d), Gov. Exh. 2.

Finally, the seventh invoice documents a March 2, 2001, purchase by Dr. Garber of testosterone from Paddock Laboratories, which was shipped to Dr. Garber's residence. *See* Gov. Exh. 45(g). Of note, the invoice gives the name "Vanessa" in the box which includes purchase order information; in the "Ship To Party Address" box, the invoice gives Dr. Garber's name followed on the next line with the notation "c/o Angela Santana." *Id.* The invoice also includes the handwritten notation: "Received by Angie 3/5/01." *Id.* Both these individuals were PSLEI employees. Tr. 598. There is no dispute that Respondent was the owner of the PSLEI when these four purchases were made.

Thereafter, on three occasions between January and March 2002, the DI (accompanied by another DI) went to PSLEI to search through its trash. Tr. 686. During the February trash run, the DIs found 50 empty boxes for a testosterone product that had been manufactured by Brovel, S.A., a Mexican firm. Tr. 709, Gov. Exh. 58. The DI subsequently had someone translate the boxes' label, which was written in Spanish. Tr. at 711. The label indicated that the testosterone was not for human consumption but rather for animal use. *See* Gov. Exh. 58, at 4; Tr. 711; *see also* Gov. Exh. 116, at 4 (declaration of FDA Associate Chief Counsel James Smith).

I do not, however, adopt the ALJ's finding that because "Respondent does not treat animals[,] * * * the records supports an inference that this non-human use testosterone was compounded into a testosterone gel which was dispensed to the Respondent's human patients." ALJ at 62. I acknowledge that the existence of the boxes does create a suspicion that the substances were dispensed to human patients. But the Government produced no additional evidence that PSLEI used this testosterone to create products that were dispensed to humans. Moreover, Respondent produced credible evidence that he performed research into the development of a more effective delivery system for testosterone. The Government did not foreclose the possibility that the testosterone was used for that purpose by producing evidence that the quantity represented by the boxes was in excess of what would be needed for research purposes. While this is a close call, it is the Government that bears the burden of proof on the issue, and I therefore conclude that the ALJ's finding is not supported by a preponderance of the evidence.

During this trash run, the DIs also found a fax for an invoice documenting PSLEI's sale of various products to a resident of Japan. *See* Gov. Exh. 70. The invoice was dated October 17, 2001, and lists "Testosterone/estradiol Gel 20 ml." and "Adrenal Extract 15 mg. # 30" as among the products sold. *Id.* As found above, PSLEI used the term "Adrenal Extract" for phentermine. Of further significance, the invoice establishes that PSLEI continued to export controlled substances following the August 23, 2001 conference and the August 31 and September 5, 2001 faxes which told Respondent to cease the exports.

Another document found during this trash run bears the caption "HORMONE DEPARTMENT PRESCRIPTION SHEET." Gov. Exh. 73. The document, which is dated October 29, 2001, makes reference to a Japanese patient and instructs a PSLEI employee to "Please ship Ms. [S.] a tube of female strength testosterone to Ginza at no charge, immediately." *Id.* The document is signed "E. Chein, M.D." *Id.*

Following a third trash run, *see* Gov. Exh. 121, DI DeSantis obtained an Administrative Inspection warrant which was executed at PSLEI on March 13, 2002. Tr. 721. During the inspection, DEA personnel asked for the biennial inventories that are required by DEA regulations. *Id.* at 759-60. The clinic did not have them, *id.* at 760, and instead provided the investigators with a document entitled "Instant Inventory Report." Gov. Exh. 82, at 7; Tr. at 760. DEA personnel also obtained dispensing logs and approximately 100 patient files for patients who lived outside the United States. *Id.* at 764 & 811.

The dispensing logs document hundreds of instances in which Respondent dispensed/exported controlled substances to residents of foreign countries. *See, e.g,* Gov. Exh. 84 (dispensing log for testosterone-estrogen (4mg.-50 mg. 20 ml.) covering period May 1, 2001, through December 31, 2001).[12] Many of the dispensings/exports occurred following the August 23rd conference and the subsequent faxes. *See id.* at pp.1-15. Moreover, the log indicates that on November 13 and 14, 2001, the day after service of the

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[12] The cover sheet of this document indicates that the period it covered was from "11/30/01-5/1/01." Gov. Exh. 84. The document, however, also includes dispensings that occurred in December 2001. *See id.* at .5 & 1.

Notice of Immediate Suspension, Respondent dispensed/exported this controlled substance thirteen times. *See id.* at 3-4.

The dispensing log for testosterone gel (0.8% 20 ml.) also documents that Respondent dispensed and/or exported following the service of the Notice of Immediate Suspension. *See* Gov. Exh. 87. Of note, Respondent dispensed to a Japanese patient on November 13, 2001, after service of the Notice of Immediate Suspension. *See id.* at 6.

The dispensing log for phentermine 15 mg. likewise documents that Respondent made numerous dispensings and/or exports of this controlled substance to foreign patients. *See generally* Gov. Exh. 88. Moreover, it also documents that Respondent made several dispensing/ exports after service of the Notice of Immediate Suspension. *See id.* For example, on November 13, 2001, Respondent made eight dispensings to foreign patients, and on November 14, 2001, Respondent made five dispensings to foreign patients. *See id.* at 6-7. Furthermore, on November 27, 2001, Respondent dispensed to a New Jersey patient. *See id.* at 6.[13] This dispensing occurred more than two weeks after service of the Notice of Immediate Suspension.

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[13] Like the dispensing logs that were obtained in February 2001, some of the logs also failed to contain the name of the dispensing physician. *See* Gov. Exh. 86, at pp. 1-29 (testosterone gel 8mg./ml., 20 ml.); Gov. Exh. 89, at 2-8 (phentermine 15 mg.).

On October 3, 2002, an additional search warrant was executed at the PSLEI. Tr. 836. During the search, DEA investigators seized approximately 83 pill containers labeled as "Adrenal Extract 15 mg," which held approximately 4300 pills, and 63 pill containers labeled as "Adrenal Extract 30mg." which held approximately 3150 pills. Gov. Exh. 135. The pills were sent to the DEA Southwest Regional Laboratory for analysis. *See id.* The lab determined that the pills contained phentermine HCL. *See id.*

During the search, DEA also seized a variety of documents. Among them is the previously described "Interoffice Memo" from Respondent, which is dated February 27, 2000, and which directed PSLEI's oral/growth hormone departments to ensure the cleanliness of the testosterone products that were shipped to Japan. Gov. Exh. 136, at 14.

The investigators also obtained several other memos on PSLEI's letterhead that were written from "Dr. Chein" on March 6, April 14, and July 3, 2000, that discuss shipments to Japan and Taiwan. *See id.* at 11-13. The memos, however, are not signed and do not indicate whether the memo was created by Respondent or his sister.

DEA also seized another memo, which is dated January 14, 2002, and which is signed "Edmund Chein MD." *Id.* at 10. The memo stated that "[e]ffective January 15th, all medicines being shipped to Tokyo goes [sic] directly to the patient address, except for patients with the chart number LEI-Y." *Id.*

The memo then directed that "[a]ll medicines for the patients with the chart number LEI-Y will be shipped directly to the Osaka clinic address[.]" *Id.* Finally, the memo directed that shipments for two patients should not be addressed "as Ever young Technologies" because the patients "have to pay taxes on the shipments that are addressed to Ever young Technologies." *Id.* Respondent prepared this memo, which is signed as having been received by an employee, following the service of the Notice of Immediate Suspension.[14]

Discussion

Respondent's Challenges to the Proceeding

In the course of this matter, Respondent filed numerous motions challenging various aspects of this proceeding. In light of my conclusion that there is no need to consider the expert testimony regarding Respondent's practices with respect to foreign patients, many of the issues raised in these motions are now moot. Respondent also filed motions seeking to dismiss various allegations or to bar the Government from introducing evidence on various issues. Upon reviewing the record, I am satisfied that the ALJ's rulings on these motions were correct and that further discussion is not warranted.

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[14] Both the Government and Respondent elicited extensive expert testimony on whether Respondent's dispensing of testosterone and phentermine to six patients who resided in foreign countries was for a legitimate medical purpose and within the usual course of professional practice. In light of Respondent's flagrant and repeated violations of federal law, I conclude that it is not necessary to make any findings on this issue.

One of the motions, however, challenges the integrity of this proceeding and therefore requires further discussion before proceeding to the merits. More specifically, Respondent alleges that the Office of Chief Counsel "engaged in a pattern of unlawful and unethical misconduct in the instant proceeding mandating the disqualification of that office." Resp. Memorandum of Points and Authorities in Support of Respondent's Motion To Disqualify Office of Chief Counsel and Dismiss Administrative Proceeding at 1. The alleged "pattern" involves two statements in an affidavit prepared by an attorney in the Office of Chief Counsel and signed by a DEA employee which discussed the circumstances surrounding DEA's failure to process Respondent's application for an Exporter's Registration. Specifically, the employee stated that she was the acting unit chief of the registration unit when she signed the declaration (and was not), and that "the reason why Dr. Chein obtained a refund of his registration fee was 'unexplained,'" Resp. Memo. at 1, when there was an explanation.

Respondent argues that this amounts to the subornation of perjury and that it "mandate[s] the disqualification of [the Office of Chief Counsel] and its replacement with * * * private counsel." *Id.* Respondent contends that this is so because "[t]he Office of Chief Counsel shall defend, cover up and represent its own interests in relation to the felony perjury charge and it will also be called to testify regarding the Respondent's Complaint that is to be filed in the District Court." *Id.* at 3.[15] Therefore, Respondent maintains that "private counsel * * * should be required to continue with any prosecution of this matter." *Id.* Respondent further asserts that it is not enough to simply "disregard" the "offending evidence" because this would not be an "effective discouragement of the wrong." *Id.* at 5. Respondent thus argues that I should take the extraordinary step of dismissing the entire proceeding which took thirteen days of hearings and produced a record that includes a nearly three thousand page transcript and hundreds of exhibits.

As a component of the Department of Justice, this agency takes most seriously allegations of employee misconduct. Respondent's offer of proof, however, falls far short of establishing that an employee of the Chief Counsel's office suborned perjury. Moreover, even if Respondent could make out a prima facie case of subornation of perjury, he offers no authority that supports his proposed remedy.

[P]roof of actual perjury is a necessary element of subornation" of perjury, *United States* v. *Hairston*, 46 F.3d 361, 376 (4th Cir. 1995), and proof of perjury requires a showing that "[a] witness testifying under oath or affirmation * * * [gave] false testimony concerning a material matter with the willful intent to provide false testimony, rather than as a result of confusion, mistake, or faulty memory." *United States* v. *Dunnigan*, 507 U.S. 87, 94 (1993). Respondent, however, cannot show either willfulness on the part of the employee or that her statements were material.

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[15] Respondent did not submit a copy of the purported "felony perjury charge" for the record. He did, however, submit a copy of a proposed complaint for a *Bivens* action.

The most common formulation" of the concept of materiality is that "a concealment or misrepresentation is material if it 'has a natural tendency to influence, or was capable of influencing, the decision of' the decisionmaking body to which it was addressed." *Kungys* v. *United States*, 485 U.S. 759, 770 (1988) (quoting *Weinstock* v. *United States*, 231 F.2d 699, 701 (D.C. Cir. 1956)) (other citation omitted); *see also United States* v. *Wells*, 519 U.S. 482, 489 (1997) (quoting *Kungys*, 485 U.S. at 770). The evidence must be "clear, unequivocal, and convincing." *Kungys*, 485 U.S. at 772; *see also Herring* v. *United States*, 424 F.3d 384, 386-87 (3d Cir. 2005) ("[A] determination of fraud on the court may be justified only by the most egregious misconduct directed to the court itself, and * * * it must be supported by clear, unequivocal and convincing evidence.") (int. quotations and citation omitted); *In re Coordinated Pretrial Proceedings in Antibiotic Antitrust Actions*, 538 F.2d 180 195 (8th Cir. 1976).

Moreover, "although the materiality of a statement rests upon a factual evidentiary showing, the ultimate finding of materiality turns on an interpretation of substantive law." *Kungys*, 485 U.S. at 772 (int. quotations and citation omitted). As the ALJ pointed out, the issues in this case are whether Respondent's continued registration as a practitioner "is inconsistent with the public interest as that term is defined in 21 U.S.C. 823(f)," and whether issuing Respondent a registration as an exporter "would be inconsistent with the public interest as that term is defined in 21 U.S.C. 958(c) and 823(d)." ALJ Notice and Order Denying Respondent's Motion to Disqualify Office of Chief Counsel and to Dismiss Administrative Proceedings, at 7. Applying these principles, I conclude that the two statements at issue here are not material to the resolution of the issues in this case.

The first allegedly perjurious statement is the employee's assertion that "I am the Acting Unit Chief of the Registration Unit," Gov. Exh. 48, when, in fact, the employee served in this capacity on the day she was approached by the attorney about Respondent's exporter application, but served in this capacity for only a few days and was not the Acting Unit Chief on the day she signed the declaration. Tr. 2198-99. The employee did, however, investigate the facts surrounding the non-acceptance of Respondent's application. Ultimately, whether the employee was still serving as Acting Unit Chief on the day she signed the declaration is of no consequence in deciding any issue in this case. In short, the assertion is not the type of statement that "has a natural tendency to influence" the decision in this case because what matters is not her specific title on the date she signed the declaration but the fact that she investigated the incident. *See Kungys*, 485 U.S. at 770 (int. quotations and other citations omitted). Moreover, Respondent has produced no evidence, let alone that which is "clear, unequivocal, and convincing" that shows that when the employee signed the declaration, she did so with the intent to deceive. *Id.* at 772.

The second allegedly perjurious statement is the employee's assertion that "[f]or an unexplained reason, DEA did not accept the application for filing" and the employee's further statement speculating that "it is likely that [Respondent] or someone from his office contacted DEA to request the refund." Gov. Exh. 48; Resp. Memo at 1. According to Respondent, the statement was perjurious because another employee had told the declarant "that a Registration Unit supervisor had instructed her to refund [Respondent's] money because he already had a DEA number" and the employee knew "that neither [Respondent] nor anyone from his office had contacted the DEA to request a refund." *Id.*

Respondent's argument as to why this statement is material to any issue in the case is somewhat opaque. Apparently, Respondent believes that there was a "mandatory" statutory duty to register him as an exporter "unless there was a finding that to do so would not be in the public interest" and that "there was no such finding" here. Reply to Govt. Resp. to Motion to Disqualify Office of Chief Counsel at 3.

Respondent further asserts that "[i]f the DEA had acted properly, and had corrected its mistake, the Respondent would have been registered." *Id.*

Under longstanding DEA policy, the approval of an application for an Exporter's registration is not a ministerial act. Rather, the application is subject to an extensive pre-registration investigation which includes a review of the six statutory factors set forth in 21 U.S.C. 823(d). *See* 21 U.S.C. 958(c). Although Respondent's application should have been processed, the violations uncovered during the January and February 2001 visits, as well as the information Respondent provided on his application regarding prior disciplinary actions of the state authorities, would have supported a finding that granting his registration would be inconsistent with the public interest. Indeed, that is why the second Show Cause Order (which proposed to deny his second application for an Exporter's registration) was issued. Respondent's assertion that his application would have been granted had DEA not mistakenly failed to process his application is thus wishful thinking.

More importantly, Federal law makes clear that "[n]o person may * * * export from the United States any controlled substance * * * unless *there is in effect* with respect to such person a registration issued by the Attorney General under section 958 of this title, or unless such person is exempt from registration under subsection(b) of this section." *Id.* section 957(a). DEA's regulations further state that "[n]o person required to be registered shall engage in any activity for which registration is required *until the application for registration is granted* and a Certificate of Registration is issued by the Administrator to such person." 21 CFR 1301.13(a) (emphasis added).

Furthermore, Federal law does not provide an exemption from registration because one has submitted an application which was subsequently mishandled. *See Dennis Robert Howard, M.D.*, 62 FR 32658, 32661 (1997) ("there is no 'good faith' exemption from liability in administrative proceedings" under the CSA). And while DEA has recognized that acting with a "good faith belief that [one is] properly registered with DEA * * * is a mitigating factor in determining the public interest," *id.*, DEA has recognized this defense in only two situations. The first is where a person had previously held a registration for the activity and believed it to be still valid pending an appeal of a final order of revocation. *See Stanley Alan Azen, M.D.*, 61 FR 57893, 57895-96 (1996). The second is where an applicant applied for a registration and received from DEA controlled substance order forms that were imprinted with a new DEA number. *See Howard*, 62 FR at 32660.[16] *Howard* is thus properly understood as a case involving reliance on an affirmative act of the government.

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[16] I decline to extend the good faith defense beyond these situations. Indeed, to do so in a case like this would create an incentive for applicants to engage in activities before they had obtained the required registration and demonstrated their fitness to perform the activity. Such a rule would clearly threaten public safety.

The good faith defense recognized in *Azen* is not applicable to Respondent's situation because Respondent never held an Exporter's Registration. Nor can Respondent claim that the allegedly perjurious statement is material under the defense recognized in *Howard*. While Respondent's application fee was refunded based on an employee's mistaken belief that Respondent already had a DEA number, *see* Resp. Memo at 1, Respondent does not claim that DEA personnel told him that he did not need a separate Exporter's registration and Respondent has produced no evidence that the application form was returned to him. Indeed, in his brief, Respondent concedes that DEA "never informed him" that his application had been rejected. Resp. Br. 24.

Furthermore, Respondent has offered no testimony to the effect that he relied on DEA's refunding of his application fee in concluding that he did not need an Exporter's registration. In fact, during the August 2001 management conference, Respondent asserted that he was not required to obtain an Exporter's registration because he qualified for a statutory exemption under 21 U.S.C. 957(b); he did not claim that he did not need the registration because his application fee had been refunded or that the application had been returned to him and that he had relied on the handwritten statement on the application. Accordingly, because Respondent makes no claim of reliance on any act of DEA, he cannot establish the materiality of the statements regarding DEA's failure to process his application.

Finally, even if Respondent had made out a prima facie case with respect to the declarant and could show that the government counsel who prepared the affidavit also intended to deceive – a point on which Respondent offers nothing more than conclusory assertions – Respondent provides no authority to support his proposed remedy of dismissing the entire proceeding. Doing so would be an especially untoward result in light of the statutory purpose to protect the public interest. Furthermore, the Government made available the declarant and Respondent was able to thoroughly examine her and demonstrate the inaccuracies in her declaration. Under these circumstances, no further relief is warranted.

The Statutory Factors

Respondent's Practitioner's Registration

Section 304(a) of the Controlled Substances Act provides that a registration to "dispense a controlled substance * * * may be suspended or revoked by the Attorney General upon a finding that the registrant * * * has committed such acts as would render his registration under section 823 of this title inconsistent with the public interest as determined under such section." 21 U.S.C. 824(a)(4). In making the public interest determination, the Act requires the consideration of the following factors:

> (1) The recommendation of the appropriate State licensing board or professional disciplinary authority.
>
> (2) The applicant's experience in dispensing * * * controlled substances.
>
> (3) The applicant's conviction record under Federal or State laws relating to the manufacture, distribution, or dispensing of controlled substances.
>
> (4) Compliance with applicable State, Federal, or local laws relating to controlled substances.
>
> (5) Such other conduct which may threaten the public health and safety.

Id. section 823(f).

"[T]hese factors are * * * considered in the disjunctive." *Robert A. Leslie, M.D.*, 68 FR 15227, 15230 (2003). I "may rely on any one or a combination of factors, and may give each factor the weight [I] deem [ ] appropriate in determining whether a registration should be revoked or an application for registration [should be] denied." *Id.* Moreover, case law establishes that I am "not required to make findings as to all of the factors." *Hoxie* v. *DEA*, 419 F.3d 477, 482 (6th Cir. 2005); *see also Morall* v. *DEA*, 412 F.3d 165, 173-74 (D.C. Cir. 2005).

Factor One – The Recommendation of the State Licensing Board

As explained above, on three occasions the Medical Board of California has imposed sanctions against Respondent. At the time the ALJ rendered her decision, the the most recent accusation had not been resolved. The ALJ nonetheless concluded that "[t]hroughout the Medical Board's proceedings, the Respondent has exhibited an unwillingness to practice medicine in a manner consistent with the California Medical Board's rules and regulations," and that Respondent's "attitude" and "conduct[ ] demonstrate that [his] continued dispensing of controlled substances is not in the public interest." ALJ at 66-67.

There is some merit to the notion that if one is not willing to comply with State law they are not likely to comply with Federal law either. I conclude, however, that it is unnecessary to decide whether a registrant's unwillingness to comply with State rules that are unrelated to controlled substances can be considered under the Act when the registrant maintains a valid State license.

In any event, the ALJ did not have the benefit of knowing the outcome of the most recent State proceeding which placed Respondent on probation for a variety of acts that included several related to his handling of controlled substances. *See* n.4. The Stipulated Settlement and Disciplinary Order further states that it "is intended to resolve * * * any disciplinary action taken by another State or the Federal government based on conduct alleged in * * * In the Matter of Edmund Chein, M.D., Docket No. 02-9 and 02-43 pending before the United States Drug Enforcement Administration." Stipulated Settlement at 2-3.

I acknowledge that the Medical Board acted within its sovereign prerogatives when it resolved matters arising under State law and decided to continue to license Respondent as a medical doctor. Moreover, a State can also adopt Federal standards as part of its State law. The Controlled Substance Act does not, however, delegate to State officials the authority to decide whether the continuation of a DEA registration is consistent with the public interest. *See* 21 U.S.C. 824. Rather, Congress entrusted that authority with the Attorney General of the United States, and that authority has been delegated solely to the officials of this Agency. *See id.*; *see also* 28 CFR 0.100(b). State officials therefore lack authority to resolve a matter pending before the Drug Enforcement Administration and the Stipulated Settlement cannot bind this agency. *See, e.g., Fourth Street Pharmacy* v. *DEA*, 836 F.2d 1137, 1139 (8th Cir. 1988).

Moreover, even viewing the stipulated settlement as, in effect, nothing more than a recommendation to continue Respondent's registration, I decline to give it deference. As will be explained below, the record is replete with evidence of Respondent's repeated and flagrant violations of Federal law. Therefore, I conclude that it would be inconsistent with the public interest to defer to the Medical Board's recommendation and give it no weight in the public interest analysis.

Factors Two and Four – Respondent's Experience in Dispensing Controlled Substances and His Record of Compliance With Laws Relating To Controlled Substances

The Dispensing and Export Violations

As the ALJ found, on March 17, 1995, and July 20, 1995, Respondent dispensed testosterone, an anabolic steroid and Schedule III controlled substance, to two undercover agents. As the record establishes, Respondent wrote each special agent a prescription for the steroids in response to each of the agent's representations that they were competitive powerlifters and were seeking the steroids to improve their performance in athletic competitions. Respondent also issued each agent a letter stating that they had been diagnosed with hypogonadism notwithstanding that he did not have the test results. Based on this evidence, I conclude that the prescriptions violated Federal law because Respondent issued them without a legitimate medical purpose. *See* 21 CFR 1306.04(a).[17]

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[17] While these incidents occurred some time ago, there is no statute of limitations applicable to these proceedings, which are remedial in nature and are instituted to protect the public interest. *See Pettigrew Rexall Drugs*, 64 FR 8855, 8859 (1999).

(Continued on following page)

The record further establishes that on February 29, 2000, Respondent directed his California employees to dispense phentermine, a Schedule IV controlled substance, to a patient in Japan. On that date, Respondent's state license had been revoked and Respondent was therefore without authority under the CSA to dispense. *See* 21 U.S.C. 802(21) ("The term 'practitioner' means a physician * * * licensed, registered, or otherwise permitted, by the United States or the jurisdiction in which he practices * * * to * * * dispense * * * ."); *id.* section 802(10) ("The term 'dispense' means to deliver a controlled substance to an ultimate user * * * by, or pursuant to the lawful order of, a practitioner * * * .").

Finally, the record establishes that Respondent repeatedly dispensed controlled substances to persons residing in foreign countries. As explained more fully below, Respondent violated Federal law because he was not registered as an exporter and did not file the required declarations. Moreover, the record shows that Respondent did so even after having been notified that his conduct was illegal. Finally, Respondent did so even after he was served with the Notice of Immediate Suspension.

While the passage of time since the wrongdoing is a factor to be considered, the statute expressly directs that a registrant's "experience in dispensing" be considered, an inquiry which necessarily requires some review of a registrant's history. If Respondent's misconduct was limited to these two instances, this would be a different case.

Respondent contends that his practitioner's registration "authorize[d] him as a registered doctor to dispense to his patient, wherever that patient is located." Resp. Exh. 75, at 4 (Resp. Memo. Pts. & Auth. in Support of Motion to Dismiss Export Charges); *see also* Resp. Br. at 22. According to Respondent, "[e]xporting and dispensing to an individual simply are two completely different matters," Resp. Exh. 75, at 3, and "[t]hese terms simply contemplate different conduct." *Id.* at 4.

Respondent further argues that under 21 U.S.C. 822(b), a registered physician is authorized to dispense to the extent authorized by his registration and in conformity with the other provisions of subchapter I. *See* Resp. Br. at 23. In Respondent's view, under the statute he was only required to comply with subchapter I, which "expressly authorizes physicians to dispense to their patients," and because the export statutes are located in subchapter II, he was not required to obtain an export registration and comply with the other requirements of that subchapter. *Id.* Perhaps recognizing how unpersuasive this argument is, Respondent further claims that the statute is ambiguous and that his interpretation of section 822(b) is reasonable. *Id.*

The starting point in statutory construction is the language of the statute. *Ardestani* v. *INS*, 502 U.S. 129, 135 (1991) (other citations omitted). Section 302(b) of the CSA provides that:

> Persons registered by the Attorney General under this subchapter to manufacture, distribute, or dispense controlled substances * * * are authorized to possess, manufacture, distribute or dispense such substances * * * to the extent authorized by their registration and in conformity with the other provisions of this subchapter.

21 U.S.C. 822(b).

As the Supreme Court has recognized, "[t]his is a qualified authorization of certain activities, not a blanket authorization of all acts by certain persons." *United States* v. *Moore*, 423 U.S. 122, 131 (1975). The statute grants a registrant authority only to perform those acts "authorized by their registration." 21 U.S.C. 822(b).

Contrary to Respondent's understanding, the "in conformity with the provisions of this subchapter" clause is a further "limitation" on a registrant's authority. *Moore*, 423 U.S. at 131. It compels a registrant to obey the requirements contained in Subchapter I. What it does not do is excuse a registrant from complying with other requirements of federal law such as those imposed by Subchapter II, the Controlled Substances Import and Export Act (CSIEA). Indeed, under Respondent's interpretation, any entity which possessed a distributor's registration would also be exempt from the requirement of obtaining an exporter's registration (as well as obtaining the permits or filing the necessary declarations) because the term "distribute" is broadly defined as "mean[ing] to deliver * * * a controlled substance," 21 U.S.C. 802(11), which is what an exporter does when it ships a product to a foreign entity.

DEA has never interpreted the Act in this manner for obvious reason – it would render the CSIEA a nullity. And contrary to Respondent's second contention that Federal law is ambiguous, both the statutes and our regulations make clear that Respondent was required to obtain an Exporter's registration to ship controlled substances to foreign countries.

Indeed, Respondent completely ignores the clear text of the Export Registration provision, 21 U.S.C. 957(a). This section expressly provides that "[n]o person may * * * export from the United States *any controlled substance* * * * unless there is in effect with respect to such person a registration issued by the Attorney General *under section 958 of this title*, or unless such person is exempt from registration under subsection(b) of this section." 21 U.S.C. 957(a) (emphasis added).

While the statute does not define the term "export," the regulations do. *See* 21 CFR 1300.01(b)(12). "The term * * * means, with respect to any article, any taking out or removal of such article from the jurisdiction of the United States (whether or not such taking out or removal constitutes an exportation within the meaning of the customs and related laws of the United States)." *Id.* Relatedly, the regulations define "[t]he term *exporter* [to] include [ ] every person who exports * * * controlled substances listed in any schedule." *Id.* 1301(b)(13). Shipping a controlled substance to a person residing in a foreign country is to take out or remove the "article from the jurisdiction of the United States," *id.* 1301(b)(12), even if the person the drug is being shipped to is an ultimate user.

Beyond that, Congress clearly stated that a person may not export a controlled substance, "unless there is in effect with respect to such person a registration issued * * * under section 958 of this title." 21 U.S.C. 957(a). A practitioner's registration is not issued under section 958, but rather under section 823(f). It thus does not provide its holder with authority to export.

Nor is there any merit to Respondent's contention that because he shipped out only small amounts of controlled substances, he was not engaged in exporting. Section 957(a) clearly provides that exporting "any controlled substance" triggers the registration requirement unless a person falls within one of the three statutory exemptions. As the plain language demonstrates, there is no threshold amount which triggers the registration requirement. Rather, to export any amount, no matter how small, a person must first obtain an exporter's registration.[18]

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[18] Indeed, each exportation was a felony under Federal law. *See* 21 U.S.C. § 960.

The exemptions to the export registration requirement also foreclose Respondent's interpretation. While the statute exempts from registration "[a]n ultimate user who possesses" a controlled substance for lawful use by themselves or a family member, this provision does not apply to Respondent. 21 U.S.C. 957(b)(1)(C). Under this exemption, an ultimate user must have the controlled substance "in his possession" at the time of export from the United States. *Id.* section 956(a)(1). Shipping controlled substances to persons in foreign countries is thus not within this exemption; the other exemptions are not remotely applicable to Respondent's conduct. *See id.* Section 957(b)(1).

DEA's Regulations also provided clear notice to Respondent that he was required to register as an Exporter. Under 21 CFR 1301.13(e), "[a]ny person who is required to be registered and who is not so registered, shall make application for registration for one of the following groups of controlled substance activities, which are *deemed to be independent of each other*." (emphasis added). The regulation then provides a table that lists each activity and the coincident activities that are permissible under a registration for a particular activity. As the table makes clear, dispensing and exporting are independent activities. *See id.* Moreover, exporting is not included in the Regulation's discussion of the "[c]oincident activities allowed" for a registration which authorizes dispensing. *See id.*

As the foregoing demonstrates, the law and regulations provided clear notice to Respondent that he could not ship controlled substances to persons residing in foreign countries without obtaining an export registration. And while it is true that Respondent was not required to obtain an Export Permit for either the testosterone or phentermine he exported,[19] he was still required to file an Export Declaration (DEA – Form 236) and submit "documentary proof that [the] importation is not contrary to the laws or regulations of the country of destination" for each shipment. 21 U.S.C. 953(e).[20]

As the record demonstrates, phentermine is a controlled substance in Belgium, Canada, Germany,

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[19] While the DI may have misinformed Respondent that he was required to obtain a permit, she did not tell him that he had no obligation to comply with Federal law.

[20] Respondent also contends that he was not required to file the declarations (DEA Form 236) because the form "requires the listing of the name and address of the 'foreign consignee/consignor,'" and that "[i]n this case, there is no 'foreign consignee/consignor,' since the recipients are end user patients." Resp. Br. 26. Respondent further contends that these "terms are used in trade to describe the persons from whom and to whom goods are shipped for sale to third parties." *Id.*

The short answer to this contention is that in common usage, the term "consignee" means "one to whom something is consigned or shipped." *Merriam-Webster's Collegiate Dictionary* 246 (10th ed. 1998). Beyond that, the record contains a copy of the "Commercial Invoice" form that Respondent used to ship products (including testosterone) to his foreign patients. Gov. Exh. 107, at 20. Under this form, which used the term "consignee," Respondent's clinic inserted the patient's name. *See id.*

Indonesia, Japan, the Republic of Korea, and Taiwan. Gov. Exh. 38(c), at 5. The record also establishes that both Japan and Taiwan prohibit the importation of this drug. *Id.* at Tabs D & E. Furthermore, testosterone is controlled in both Canada and the United Kingdom. *See id.* at 5.

Respondent's failure to declare these shipments to DEA prevents the United States from fulfilling its treaty obligations and denies the country of destination the opportunity to determine whether a shipment of a controlled substance is permissible before it occurs. *See id.* at 3. It thus undermines the system of international cooperation to prevent the illegal flow of controlled substances. *See, e.g., Convention on Psychotropic Substances*, 1971, Art. 21 ("[T]he Parties shall * * * [a]ssist each other in the campaign against the illicit traffic in psychotropic substances * * * [and] [c]o-operate closely with each other * * * with a view to maintaining a co-ordinated campaign against the illicit traffic.").

Respondent further contends that he acted in good faith to obtain an Export registration. But as explained above, Federal law makes clear that "[n]o person may * * * export from the United States any controlled substance * * * unless [a registration] is in effect," 21 U.S.C. 957(b), and the regulations further provide that a person cannot "engage in any activity for which registration is required until the application * * * is granted and a Certificate of Registration is issued." 21 CFR 1301.13(a). Determining whether the granting of an application for an export registration is consistent with the public interest requires an extensive and time consuming investigation into the same criteria that apply to manufacturers. 21 U.S.C. 958(c) & 823(d). Granting such a registration is not a ministerial act, and in this case, the conduct uncovered before Respondent even applied for the registration was enough to deny his application.

Furthermore, the record establishes that Respondent subsequently acted with deliberate disregard for the requirements of federal law. Both during the August 2001 management conference, and in several faxes thereafter, Respondent was warned by the DI to stop the foreign shipments. He nonetheless continued to send controlled substances to persons in foreign countries. Furthermore, notwithstanding the service of the Notice of Immediate Suspension of his registration, Respondent made further dispensings of controlled substances to persons who resided both within the U.S. and abroad. Respondent's conduct demonstrates that he acted with a deliberate disregard for the law.

The Import Allegations

The record also contains evidence suggesting that Respondent obtained testosterone products from Mexico. This evidence includes the invoice which Respondent gave the DI during the August 2001 management conference. Specifically, the invoice, which was dated June 26, 2001, indicated that PSLEI had purchased 120 units of Depo testosterone and 40 units of Decadurabolin from Farmacias Castaneda, which listed its address as Tijuana, Mexico. Gov. Exh. 22. Moreover, during the February 2002 trash run, the DIs found 50 empty boxes of a testosterone product that had been manufactured by Brovel, S.A., a Mexican firm. Tr. 709, Gov. Exh. 58.

The ALJ concluded that the Government had failed to prove that Respondent "received imported controlled substances from Mexico," apparently because the record "contains evidence that the owner of the Mexican pharmacy, Dr. Romero, may have shipped the controlled substances from a location in San Diego." ALJ 75. The ALJ further explained that "[t]here are no shipping documents in the record to refute this evidence." *Id.*

Romero was not, however, a registered importer. And even accepting the ALJ's finding that the drugs may have been shipped to Respondent from a location in San Diego, I do not find persuasive the ALJ's reasoning that Respondent therefore did not engage in importation. Indeed, I conclude that the ALJ's reasoning is contrary to well settled authority and that adopting it would gut Federal drug laws.

"Importation is a continuing crime that is not complete until the controlled substance reaches its final destination." *United States* v. *Camargo-Vergara*, 57 F.3d 993, 1001 (11th Cir. 1995); *see also United States* v. *Martinez*, 763 F.2d 1297, 1304 (11th Cir. 1985). The fact that someone else brought the drugs across the border, or that the drugs were shipped from a way station within the United States, does not make the final intended recipient any less an importer. As the Fifth Circuit has explained, one "need not have participated directly in the physical movement of the [controlled substance] across the border to be convicted under 21 U.S.C. 952(a)." *United States* v. *Lopez-Escobar*, 920 F.2d 1241, 1245 (1991). Indeed, drug dealers frequently use third parties to smuggle controlled substances into this country. That does not make them any less an importer.

Rather, the Government need only show that "the defendant knowingly played a role in bringing the substance from a foreign country into the United States," *United States* v. *Jackson*, 55 F.3d 1219, 1225 (6th Cir. 1995); or that "the defendant either imported the substance or caused it to be imported." *United States* v. *Nusraty*, 867 F.2d 759, 766 (2d Cir. 1989); *Accord United States* v. *Samad*, 754 F.2d 1091, 1096 (4th Cir. 1984). *See also United States* v. *Diaz-Carreon* 915 F.2d 951, 953 (5th Cir. 1990). The Government's proof satisfies either standard.

The Farmacia Castaneda invoice clearly establishes that: (1) Two controlled substances were shipped to Respondent, and (2) that the source of the controlled substances was a Mexican based pharmacy notwithstanding that the substances may have been shipped from Mr. Romero's San Diego address. The invoice further establishes that (3) Respondent caused the controlled substances to be imported by ordering them from the pharmacy. Finally, Respondent does not dispute that he received these two controlled substances but rather only whether the substances "came from San Diego, [and] not Mexico." Resp. Proposed Findings at 14. The record thus contains substantial evidence that Respondent imported controlled substances.

Under Federal law, "[n]o person may * * * import into the United States from any place outside thereof, any controlled substance * * * unless there is in effect with respect to such person a registration issued * * * under section 958 of this title" or the person "is exempt from registration under subsection(b)." 21 U.S.C. 957(a). Respondent was not registered as an importer, Gov. Exh. 2, and does fall within any of the three exemptions. *See* 21 U.S.C. 957(b). I thus conclude that Respondent violated federal law when he imported depo testosterone and decadurabolin from Mexico without being registered to do so.[21]

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[21] I have reviewed Respondent's contention that these allegations should be dismissed because they were not alleged in the Order to Show Cause. While it is true that our regulations and the Administrative Procedure Act require that an Order to Show Cause contain "a summary of the matters of fact and law asserted," 21 CFR 1301.37(c), an agency is not required "to give every [Respondent] a complete bill of particulars as to every allegation that [it] will confront." *Boston Carrier, Inc.* v. *ICC*, 746 F.2d 1555, 1560 (D.C. Cir. 1984).

Having reviewed the pre-hearing statements, I conclude that the Government gave Respondent fair notice that the import allegations would be raised and litigated. I further conclude that Respondent had "a meaningful opportunity to litigate the * * * issue in the hearing itself." *NLRB* v. *Blake*

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The Record Keeping Violations

The record further establishes that Respondent committed numerous recordkeeping violations. Beginning with the 1994-95 investigation, during the execution of the search warrant, none of the required records were found even though Respondent had purchased a variety of controlled substances included various anabolic steroids and diazepam.

Moreover, on January 31, 2001, DEA visited Respondent's clinic and requested to see its controlled substance records. The invoices for the purchase of controlled substance were not on-site, but rather were at the office of the clinic's accountant. This violated 21 CFR 1304.04(a). Moreover, the inventory records and dispensing logs were stored in a computer system and no one was present at the clinic who could access them. Tr. 269.

DEA regulations require that "each registered individual practitioner required to keep records" shall maintain the records "either separately from all other records of the registrant or in such form that the information required is readily retrievable from the ordinary business records of the registrant." 21 CFR

Construction Co., Inc., 663 F.2d 272, 279 (D.C. Cir. 1981). The Government's refusal to turn over FedEx documents that would have shown that the two controlled substances had been shipped from Romero's San Diego location did not deny Respondent a meaningful opportunity to litigate the issue; indeed, I accept that the steroids may have been shipped to Respondent from a San Diego address.

1304.04(g) & (f)(2). As relevant here, DEA regulations define the term "readily retrievable" to mean "that certain records are kept by automatic data processing systems or other electronic or mechanized recordkeeping systems in such a manner that they can be separated out from all other records *in a reasonable time.*" *Id.* § 1300.01(b)(38) (emphasis added).

Respondent is correct that this regulation does not require that records be "instantaneously produced." Resp. Br. 9. Moreover, the record does not indicate how long DEA personnel were at the clinic during the January 31, 2001 visit. Accordingly, there is no basis to conclude that the inventory and dispensing records were not readily retrievable on that date.

I nonetheless note Respondent's argument that he "was not required to produce his records on the same day as the DEA's demand." *Id.* at 17. This is so, Respondent contends, because "[n]either the statute nor the regulation prescribes a time limit within which a practitioner must produce his controlled substance records upon the DEA's request to examine them." *Id.*

The regulation does, however, require that records be retrievable in "a reasonable time." While what constitutes "a reasonable time" necessarily depends on the circumstances, under normal circumstances if a practice is open for business, it should be capable of producing a complete set of records within several hours of the request. In this case, I conclude that on the second visit, the clinic's provision of the records within two to three hours complied with the regulation but barely so. To allow a registrant an even greater period of time to produce the records would create an incentive for those who are engaged in illegal activity to obstruct investigations by stalling for time in the hopes that DEA personnel would eventually give up and leave.

Most significantly, the records that were provided did not comply with DEA's regulations. The "inventory report" was dated February 5, 2001. It did not include a DEA number for either Respondent or his associate and did not indicate that it had been done at the opening or closing of business. 21 CFR 1304.03(a) & 1304.11(a). Furthermore, the dispensing logs did not reflect the name of the dispensing registrant. *Id.* § 1304.03(b). Moreover, the logs covered only a period of approximately seven months and not the required two years. *Id.* § 1304.04(a). Finally, no invoices for testosterone were provided even though the other records clearly showed that the PSLEI had testosterone products on hand and was actively dispensing them. *Id.* § 1304.21(a).

Nor were Respondent's recordkeeping violations limited to this time period. During the March 2002 Administrative Inspection, DEA personnel again requested to inspect Respondent's records including the required inventories. While Respondent was not available, the clinic could not provide the required inventories for the various controlled substances that were being dispensed. *See* ALJ 23.

Other Violations

The record contains evidence of further violations of DEA regulations during the period of Respondent's ownership. In March 2001, Respondent's clinic used Connie Chein's DEA number to order controlled substances even though Ms. Chein did not practice at the clinic and the clinic was not her registered location. *See* Gov. Exh. 45(a). This was a violation of 21 U.S.C. 843(a)(2) (prohibiting use of a registration number "issued to another person" for purpose of obtaining controlled substances). Moreover, Respondent's employees ordered controlled substances for the clinic using Dr. Garber's registration and had them shipped to Dr. Garber's residence, which was no longer a registered location. *See* Gov. Exh 45(b), (c), (d) & (g). This conduct undermines the CSA's closed system of distribution which requires that a registrant maintain a registration at each place of business from where a registrant distributes controlled substances. 21 U.S.C. 822(e); 21 CFR 1301.12. Under DEA precedents, a registrant is responsible for violations of the CSA committed by his employees and his practice's failure to comply with the Act. *See Leonard Merkow*, 60 FR 22075, 22076 (1995).

In conclusion, the evidence of Respondent's noncompliance with applicable laws related to controlled substances is extensive and shocking. Taken as a whole, Respondent's record reflects a flagrant disregard for the requirements of Federal law. Accordingly, I conclude that Respondent's continued registration as a practitioner would be inconsistent with the public interest.[22]

Respondent's Export Application

Section 1008 of the Controlled Substances Act provides that "[t]he Attorney General may deny an application for registration [to export controlled substances in schedule III or IV] * * * if he determines that such registration is inconsistent with the public interest * * * or with the United States obligation under international treaties, conventions, or protocols in effect on May 1, 1971." 21 U.S.C. 958(d)(2). In making the public interest determination for an application to export Schedule III and IV controlled substances, Congress further directed that the Attorney General consider the factors applicable to manufacturers of Schedule III through V controlled substances. *Id.* section 958(c)(1). The factors are:

> (1) Maintenance of effective controls against diversion of particular controlled substances and any controlled substance in schedule III, IV or V compounded therefrom

---

[22] I acknowledge that Respondent has not been convicted under either Federal or State law of a controlled substances offense. Given Respondent's extensive record of non-compliance with applicable laws, this factor is entitled to no weight. Moreover, because Respondent's record of violations is extensive enough to support the revocation of his registration, it is not necessary to discuss whether he engaged in other conduct which threatens public health and safety.

> into other than legitimate medical, scientific, or industrial channels;
>
> (2) Compliance with applicable State and local law;
>
> (3) Promotion of technical advances in the art of manufacturing these substances and the development of new substances;
>
> (4) Prior conviction record of applicant under Federal or State laws relating to the manufacture, distribution, or dispensing of such substances;
>
> (5) Past experience in the manufacture, distribution, and dispensing of controlled substances, and the existence in the establishment of effective controls against diversion; and
>
> (6) Such other factors as may be relevant to and consistent with the public health and safety.

21 U.S.C. 823(d). As with the public interest determinations applicable to other categories of registrants, "these factors are * * * considered in the disjunctive." *ALRA Laboratories, Inc.*, 59 FR 50620, 50621 (1994). I "may * * * rely on any one or a combination of factors, and give each factor the weight [I] deem appropriate" in considering whether to grant Respondent's application. *Id.* Moreover, case law establishes that I am "not required to make findings as to all of the factors." *Hoxie*, 419 F.3d at 482.

Here, while Congress has directed a slightly different analysis than that applicable to Respondent's practitioner's registration, I conclude that the same reasons that support the revocation of that registration also require the conclusion that granting Respondent's application for an export registration would be inconsistent with the public interest. There is no need to engage in a lengthy rehashing of those factors (such as Respondent's past experience and lack of compliance with Federal law) which have already been discussed; that discussion is therefore incorporated by reference.

Both factors one and five inquire into whether an applicant has effective controls against diversion. Respondent clearly does not as demonstrated by his clinic's repeated failure to provide DEA with either initial or biennial inventories that complied with the regulations. Accurate inventories are essential to conduct accountability audits and to determine whether diversion has occurred.

Respondent asserts that "[t]here was no diversion of controlled substances from the legitimate chain of distribution." Resp. Br. 6. That is not so. The record contains abundant evidence that phentermine was sent to patients in Japan, Korea, and Taiwan. *See* Gov. Exh. 128. As demonstrated by a letter from a Japanese Ministry of Health official, it was illegal to export phentermine to Japan (although a person is allowed to bring in a small amount of the drug on his person). *See* Gov. Exh. 38(C). Furthermore, Taiwan had prohibited the use of phentermine and its importation. Finally, the record indicates that it is illegal to prescribe phentermine for anti-aging purposes in Korea and Japan.

Both Japan and the United States have ratified the 1971 Convention on Psychotropic Substances, which regulates phentermine; the Republic of Korea has also become a party to the Convention by accession.[23] As explained above, under the Convention, the United States agreed to undertake certain measures including assisting other parties "in the campaign against the illicit traffic in psychotropic substances." Convention on Psychotropic Substances Art. 21(b).

In light of the authority that an export registration grants, as well as our treaty obligations, it is appropriate to consider the potential impact of Respondent's conduct not only on this country, but also on other parties to the Convention.[24] The statements

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[23] Taiwan was also a signatory to the Convention on Psychotropic Substances. It is acknowledged that Republic of China has declared Taiwan's ratification of the Convention to be null and void.

[24] *Noramco* v. *DEA*, 375 F.3d 1148, 1156 (D.C. Cir. 2004), is not to the contrary. That case involved an assertion by a competitor of a domestic manufacturer that granting the latter an importer's registration would lead to increased diversion of narcotic raw materials in India, the country of origin. *See Penick Corp., Inc.*, 68 FR 6947, 6951 (2003). While this assertion was entirely speculative, my predecessor further ruled that DEA was not required to consider the impact on diversion in the country of origin. *See id.* In affirming that interpretation as a reasonable construction of the statute, the court of appeals reasoned that

(Continued on following page)

of various government officials regarding the prohibition on the exportation of phentermine to their countries, as well as other evidence that it is illegal to prescribe phentermine for anti-aging purposes in several of these countries, establish that Respondent's exports of phentermine to foreign patients were not within the legitimate chain of distribution and were not for a legitimate medical purpose. The shipments thus establish that Respondent has engaged in diversion. I therefore conclude that Respondent's past experience in distributing and dispensing controlled substances demonstrates that his practice lacks effective controls against diversion – indeed, he is the cause of the diversion – and that this factor further supports a finding that granting Respondent's application would be inconsistent with the public interest. For the same reason, factor one supports a finding that granting Respondent's application would be inconsistent with the public interest.

"Congress was concerned with preventing diversion in this country rather than abroad." 375 F.3d at 1156.

Here, however, Federal law expressly requires that an exporter, before exporting any nonnarcotic controlled substance in schedules III or IV, "furnish" to DEA "documentary proof that importation is not contrary to the laws or regulations of the country of destination for consumption for medical, scientific, or other legitimate purposes." 21 U.S.C. 953(e)(1). Thus, in contrast to the situation at issue in *Penick*, here, other provisions of the CSIEA suggest that in assessing Respondent's application, it is appropriate to consider the potential for diversion of the controlled substance in the destination country.

The ALJ found that Respondent has promoted technical advances in the development of new substances (Factor 3) as demonstrated by his obtaining of several patents including one for his total hormone replacement therapy. *See* ALJ at 80. The ALJ further concluded that granting Respondent an export registration "would enhance his ability to continue to develop [the] therapy for his patients." *Id.*

I acknowledge that Respondent has obtained various patents for his treatment regimen and had applied for a patent for a particular testosterone composition. *See* Resp. Ex. 1016. Even so, Respondent's contributions in this area are greatly outweighed by his record of misconduct and his flagrant disregard for the requirements of federal law. This factor is thus entitled to no weight. I further note, however, that denying Respondent's application for an export registration (and revoking his practitioner's registration) does not preclude him from developing new treatment protocols. Respondent can continue to do so as long as he limits his research to noncontrolled substances.

Finally, in discussing other relevant factors (Factor 6), the ALJ found "that the public has an interest in the continued access to Respondent's total hormone replacement therapy," and suggested that I could consider this in deciding whether to deny Respondent's application for an export registration (as well as to revoke his practitioner's registration). ALJ at 81. I need not decide whether this is an appropriate consideration under the statute because even if it is, Respondent's extensive history of misconduct clearly outweighs any benefit to the public that would accrue from allowing Respondent to handle controlled substances as either an exporter or practitioner. And in any event, Respondent can always license his patents to other physicians or offer to teach them his medical discoveries.

Considering all of the factors, I conclude that Respondent's past experience in distributing and dispensing controlled substances is entitled to dispositive weight in the public interest determination applicable to his application for registration as an Exporter. Because that experience manifests a sustained and flagrant disregard for the requirements of Federal law, I conclude that granting Respondent's application would be inconsistent with the public interest.[25]

Order

Pursuant to the authority vested in me by 21 U.S.C. 823(f) & 824(a), as well as 28 CFR 0.100(b) & 0.104, I hereby order that DEA Certificate of Registration, AC1643661, issued to Edmund Chein, M.D., be, and it hereby is, revoked. I also order that any pending applications for renewal or modification of such registration be, and they hereby are, denied.

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[25] Even if the Court of Appeals was to disagree with my finding that Respondent was still in charge of the Palm Springs clinic's dispensation of controlled substances during the period of his sister's putative ownership, the scope of his misconduct during the periods in which he owned the clinic is so extensive and egregious that I would still revoke his practitioner's registration and deny his exporter's application.

Pursuant to the authority vested in me by 21 U.S.C. 958(d), as well as 28 CFR 0.100(b) & 0.104, I further order that the application of Edmund Chein, M.D., for a DEA Certificate of Registration as an Exporter of controlled substances be, and it hereby is, denied.

Dated: January 19, 2007.

Michele M. Leonhart,

Deputy Administrator.

[FR Doc. E7-2217 Filed 2-9-07; 8:45 am]

BILLING CODE 4410-09-P

DEPARTMENT OF LABOR

Employee Benefits Security Administration

[Prohibited Transaction Exemption 2007-03; Exemption Application No. D-11381]

Grant of Individual Exemption Involving The Bear Stearns Companies, Inc. (BS), Bear Stearns Asset Management Inc. (BSAM), and Bear, Stearns & Co. Inc. (BSC) (Collectively, the Applicants) Located in New York, NY

AGENCY: Employee Benefits Security Administration, U.S. Department of Labor

ACTION: Grant of individual exemption.

SUMMARY: This document contains a final exemption issued by the Department of Labor (the Department) that provides relief from certain prohibited transaction restrictions of the Employee Retirement Income Security Act of 1974 (the Act) and the Internal Revenue Code of 1986 (the Code). The exemption permits the purchase of certain securities (the Securities), by an asset management affiliate of BS from any person other than such asset management affiliate of BS or any affiliate thereof, during the existence of an underwriting or selling syndicate with respect to such Securities, where a broker-dealer affiliated with BS (the Affiliated Broker-Dealer) is a manager or member of such syndicate and the asset management affiliate of BS purchases such Securities, as a fiduciary: (a) On behalf of an employee benefit plan or employee benefit plans (Client Plan(s)); or (b) on behalf of Client Plans, and/or in-house plans (In-House Plans) which are invested in a pooled fund or in pooled funds (Pooled Fund(s)); provided certain conditions as set forth, below are satisfied (An affiliated underwriter transaction (AUT)).[1] The exemption affects Client Plans and In-House Plans and their participants and beneficiaries.

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[1] For purposes of this exemption an In-House Plan may engage in AUT's only through investment in a Pooled Fund.

EFFECTIVE DATE: This exemption is effective as of the date it is published in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: Angelena C. Le Blanc, Office of Exemption Determinations, Employee Benefits Security Administration, U.S. Department of Labor, telephone (202) 693-8540. (This is not a toll-free number.)

SUPPLEMENTARY INFORMATION: On November 24, 2006, the Department published a Notice of Proposed Exemption (the Notice) in the **Federal Register** at 71 FR 67904. The document contained a proposed individual exemption from the restrictions of section 406 of the Act and section 4975(c)(1)(A) through (F) of the Code. The proposed exemption had been requested in an application filed by the Applicants, pursuant to section 408(a) of the Act, and in accordance with the procedures set forth in 29 CFR Part 2570, Subpart B (55 FR 32836, August 10, 1990). Effective December 31, 1978, section 102 of Reorganization Plan No. 4 of 1978 (43 FR 47713, October 17, 1978) transferred the authority of the Secretary of the Treasury to issue exemptions of the type requested to the Secretary of Labor. Accordingly, this exemption is being issued solely by the Department.

The proposed exemption gave interested persons an opportunity to comment and to request a hearing. In this regard, all interested persons were invited to submit written comments or requests for a hearing on the pending exemption on or before January 8, 2007.

The Applicants informed the Department in a letter dated January 5, 2007, that the Notice along with the supplemental statement (the Supplemental Statement), described at 29 CFR 2570.43(b)(2) of the Department's regulations, was sent by December 9, 2006, via first class mail to all Interested Persons with the exception of two (2) such Interested Persons. The Applicant further informed the Department that the Notice and the Supplemental Statement was sent by December 13, 2006, via first class mail to these two (2) remaining Interested Persons. In light of the fact that notification to these Interested Persons was delayed and in order to allow such Interested Persons the benefit of the full thirty (30) day comment period, the Department required, and the Applicants agreed to, an extension of the deadline within which these two (2) Interested Persons could comment or request a hearing on the proposed exemption. In this regard, in accordance with the Department's instructions, the Applicants sent a letter on December 19, 2006, to these Interested Persons notifying them that the comment period was extended until January 15, 2007. All comments were made part of the record.

During the comment period, the Department received no requests for a hearing. The Department did receive a comment letter from the Applicants. The written comments and the responses are discussed below.

Written Comments

In a letter dated, January 5, 2007, the Applicants' suggested revisions of the language in paragraph 19 of the Summary of Facts and Representations, as published in the Notice at 71 FR 67907, column 1, lines 58-69, and column 2, lines 1-22, in order to reflect changes in the law regarding "hot issues."

The Department concurs with the Applicants' suggested revisions. In this regard, paragraph 19 of the Summary of Facts and Representations, as set forth in the Notice, should have read as follows:

19. Assuming that the marketing efforts have produced sufficient indications of interest, the Applicants represent that the issuer of the securities and the selling syndicate managers together will set the price of the securities and ask the SEC to declare the registration effective. After the registration statement becomes effective and the underwriting agreement is executed, the underwriters contact those investors that have indicated an interest in purchasing securities in the offering to execute the sales. The Applicants represent that offerings are often oversubscribed, and many have an over-allotment option that the underwriters can exercise to acquire additional shares from the issuer. Where an offering is oversubscribed, the underwriters decide how to allocate the securities among the potential purchasers. However, pursuant to the National Association of Securities Dealers Rule 2790, new

issue securities (as defined under such rule) may not be sold directly to:

* * *

UNITED STATES DEPARTMENT OF JUSTICE
Drug Enforcement Administration

In the Matter of **EDMUND CHEIN, M.D.**	**Docket No. 02-9,** **Docket No. 02-43**

RECOMMENDED FINDINGS OF FACT, CONCLUSIONS OF LAW, AND DECISION OF THE ADMINISTRATIVE LAW JUDGE

Gail A. Randall, Administrative Law Judge

DATED: July 28, 2005

APPEARANCES:

Wayne M. Patrick, Esq.
for the Government

Philip Boesch, Esq.
for the Respondent

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I. PROCEDURAL BACKGROUND

On November 7, 2001, the Administrator of the Drug Enforcement Administration ("DEA") issued an Order to Show Cause ("Order I") to Edmund Chein, M.D. ("Respondent"), seeking to revoke his DEA Certificate of Registration AC1643661, as a practitioner, and to deny any pending applications for renewal or modification of such registration pursuant to 21 U.S.C. sections 823(f) and 824(a) because his continued registration would be inconsistent with the public interest, as that term is used in 21 U.S.C. § 823(f). Order I also suspended the Respondent's registration, finding that to continue his registration would create an imminent danger to the public health or safety pursuant to 21 U.S.C. §824(d). The Respondent timely filed a request for a hearing on the allegations raised by Order I. [ALJ Exh. 4].

On May 24, 2002, the Deputy Assistant Administrator, Office of Diversion Control, DEA, issued another Order to Show Cause ("Order II") to Dr. Chein, seeking to deny his application for a DEA Certificate of Registration as an exporter, and to deny any pending requests for modification, pursuant to 21 U.S.C. §§ 958(c) and (d), because to grant his DEA application for registration would be inconsistent with the public interest. [ALJ Exh. 1]. The Respondent timely filed a request for a hearing on the allegations raised by Order II. [ALJ Exh. 3].

On March 5, 2002, I held a preheating teleconference with both parties to establish the remaining prehearing filing schedule and to establish a hearing date and location. [ALJ Exh. 5]. The requested hearing was scheduled to commence in Riverside, California, on July 9, 2002. [ALJ Exh. 6]

However, on June 6, 2002, the parties filed a Joint Motion for Consolidation and Continuance, moving to consolidate and continue the two cases docketed at 02-9 (from Order I) and 02-43 (from Order II). [ALJ Exh. 7]. By order dated June 13, 2002, I granted the consolidation motion and the motion for a continuance. [ALJ Exh. 8].

By order dated September 18, 2002, I issued a Supplemental Prehearing Ruling, establishing another prehearing schedule. [ALJ Exh. 9]. The requested hearing was held in Riverside, California, on January 28, 2003, through February 6, 2003. [ALJ Exh. 10; Transcript ("Tr.") Volumes I-VIII]. During this portion of the hearing, the Respondent objected to DEA's jurisdiction pertaining to the issue of medical standard of care, as the Respondent styled the objection. [Tr. at 442-443]. Although the ALJ overruled the Respondent's objection, she granted the Respondent permission to take an interlocutory appeal of this issue. [Tr. at 490-497, 1180-1193]. The ALJ also ruled that the Government's expert witness would not be permitted to testify at this portion of the hearing, pending the ruling on the interlocutory appeal. [Tr. at 1193].

On June 23, 2003, the Acting DEA Administrator issued an Interlocutory Order, denying the

Respondent's motion and holding that DEA could litigate the issues relating to the medical practices engaged in by the Respondent. [ALJ Exh. 19][1]

A second segment of this case was heard on September 9 through September 10, 2003, at DEA Headquarters in Arlington, Virginia. [ALJ Exh. 15]. The final segment of this case was heard in Riverside, California, on December 9 through December 11, 2003. [ALJ Exh. 17, Tr. Volumes X-XII].

At all of the hearings, both parties called witnesses and introduced documentary evidence. After the hearing, both parties submitted Proposed Findings of Fact, Conclusions of Law and Argument.

II. ISSUES

The issues in this case are:

Whether or not the record as a whole establishes by a preponderance of the evidence that the DEA should revoke the DEA Certificate of Registration of Dr. Edmund Chein and deny any pending applications to renew this registration pursuant to 21 U.S.C. § 824(a)(4), because Dr. Chein's continued registration is inconsistent with the public interest as that term is defined in 21 U.S.C. § 823(f); and

Whether or not the record as a whole establishes by a preponderance of the evidence that the Drug

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[1] By this Order, I hereby admit ALJ Exh. 19 into the record.

Enforcement Administration should deny Dr. Edmund Chein's pending application for a DEA Certificate of Registration as an exporter, and deny any pending applications to modify any existing registrations, pursuant to 21 U.S.C. §§ 958(c) and (d), because to issue such a registration would be inconsistent with the public interest as that term is defined in 21 U.S.C. §§ 958(c) and 823(d)(1-6).

III. FINDINGS OF FACT

A. Stipulated Facts

The parties have stipulated to the following facts:

1. Respondent is registered with DEA as a practitioner, under DEA No. AC1643661, to dispense controlled substances in Schedules II, II-N, III, III-N, IV and V.

2. Anabolic steroids are Controlled Substances under Schedule III of the Controlled Substances Act pursuant to 21 C.F.R. § 1308.13(f)(1), Drug Code No. 4000.

3. Phentermine is a Controlled Substance under Schedule IV of the Controlled Substances Act pursuant to 21 C.F.R. § 1308.14(e)(9), Drug Code No. 1640.

4. Testosterone, Testosterone Powder, Depo Testosterone, Testosterone Estradiol Gel, Testosterone Gel, Sublingual Testosterone, and Decadurabolin are anabolic steroids and are Schedule III Controlled Substances.

5. The following substances listed in Respondent's Inventory Report and Dispensing Records, dated 2/5/01, are Schedule III Controlled Substances: Depo Testosterone 200 mg/ml; Testosterone Estradiol Gel 4 mg/ml, 5%; Testosterone Gel 100 mg/ml; and Testosterone Gel 8 mg/ml.

6. The following substances listed in Respondent's Dispensing Records, dated 2/5/01, are Schedule III Controlled Substances: Sublingual Testosterone 50 mg; Testosterone 50 mg/100 mg tube.

7. The following substance listed on invoices for product sent to Respondent is a Schedule III Controlled Substance: Testosterone Powder.

8. The following substances listed in Respondent's Inventory Report and Dispensing Records, dated 2/5/01, are Schedule IV Controlled Substances; Phentermine 15 mg and Phentermine 30 mg.

9. Respondent's registered address is 2825 Tahquitz Canyon Building A, Palm Springs, CA, 92262.

10. DEA mailed to Respondent a letter dated March 6, 2000, requesting that Respondent voluntarily surrender his DEA registration.

11. On July 20, 2000, Respondent submitted a Request for Renewal Application, DEA Form 224a, to renew Respondent's DEA controlled substance registration.

12. The address listed on Respondent's renewal form was 201 South Main, Suite 900, Salt Lake City, UT, 84111.

13. On March 5, 2001, DEA received a letter from Respondent requesting to modify the address identified on his renewal application. In lieu of the Utah address listed on the renewal application, Respondent sought to register at 2825 Tahquitz Canyon Way, Building A, Palm Springs, CA, 92262.

14. Connie Chein, M.D. is Respondent's sister.

15. Connie Chein, M.D. is registered with the DEA as a practitioner to handle Controlled Substances under DEA No. AC7093292.

B. Facts Regarding Revocation Action

(1) *Respondent's Medical Practices*

16. The Respondent is a medical doctor with a law degree. [Tr. 659].

17. As an anti-aging practitioner, among other things the Respondent handles testosterone, which is a non-narcotic anabolic steroid regulated as a Schedule III controlled substance. [Tr. 109-110, 517]. Consistently, all of the records pertaining to the Respondent's medical practice, Palm Springs Life Extension Institute ("PSLEI"), indicate that the Respondent is handling non-narcotic controlled substances. [Tr. 1022, 1287, 1536].

18. Controlled substances were kept at PSLEI in two areas: a micro-pharmacy room and in a compounding room. [Tr. 760-761]. In the compounding room, personnel from PSLEI mix up testosterone gel for patients, and, after it is prepared, it is stored in the micropharmacy room until it is dispensed to patients. [Tr. 761]. These products were also shipped to patients from PSLEI's mailing room. [Tr. 763]. All of the medical assistants had access to these rooms and the controlled substances stored therein. [Tr. 1496]. The substances were not sorted and stored according to each doctor practicing at PSLEI. Rather, the controlled substances were all lumped together. [Tr. 1498].

19. The Respondent has a "world-wide" medical practice, with patients residing overseas. [Tr. 1235-1236]. He has made extensive visits to Korea and Japan. [Tr. 1045-1046, 1235]. He also had a web site and advertised his practice on that site. [Tr. 1237].

20. Generally, the record demonstrates that the Respondent shipped small quantities of controlled substances specifically for his patients' use. [Tr. 966-967].

21. The record reflects that the Respondent had approximately ten employees, to include Dr. Daryl Garber, Mr. Marshall Gilbert, and Ms. Vanessa Koloen. [Tr. 1331, 1349, 1610].

(2) *Dr. Connie Chein's Involvement with PSLEI*

22. Dr. Connie Chein ("Dr. C. Chein") is a medical doctor, board certified and practicing obstetrics and gynecology. [Resp. Exh. 1072; Tr. 1065-1067]. Her medical practice is located in Beverly Hills, California. [Tr. 1067]. She only treats female patients. [Tr. 1073].

23. On December 13, 2001, Dr. C. Chein was interviewed at her office by DEA Diversion Investigator ("DI") Doris DeSantis. [Tr. 1080]. Dr. C. Chein's attorney was also present. Dr. C. Chein tape recorded the conversation, and provided the DEA with a copy of the tape. [Tr. 1080-1081]. The DEA made a transcript of the recording. [Govt. Exh. 28; Tr. 1080-1081].

24. On or about February 16, 2000, Dr. C. Chein purchased PSLEI from her brother, the Respondent in this case. [Tr. 1087, 1297-1298]. In December of 2000, she sold PSLEI back to her brother. [Tr. 1087; Govt. Exhs. 142, 143].

25. Dr. C. Chein never gave the Respondent permission to use her DEA registration. [Govt. Exh. 28 at 15].

26. Dr. C. Chein never received controlled substances shipped to her registered location but intended for PSLEI. [Govt. Exh. 28 at 16, 19].

27. During 2000, Vanessa Koloen and Marshall Gilbert were the managers of PSLEI. [Tr. 1089-1090].

28. Dr. C. Chein never treated patients at PSLEI. [Tr. 1092]. When asked at the hearing if she ever prescribed or dispensed controlled substances at PSLEI, she asserted her Fifth Amendment rights and refused to answer the question. [Tr. 1093].

29. When asked at the hearing if she ever ordered controlled substances for treatment of patients at PSLEI, Dr. C. Chein asserted her Fifth Amendment rights and refused to answer the question. [Tr. 1094].

30. At the hearing, Dr. C. Chein was handed invoices from suppliers of controlled substances to PSLEI. However, she asserted her Fifth Amendment rights and refused to answer any questions concerning these invoices. [Tr. 1111-1112, 1116-1119; Govt. Exhs. 17, 20].

31. At the hearing, Dr. C. Chein was handed purchase orders to suppliers of controlled substances to PSLEI. However, she asserted her Fifth Amendment rights and refused to answer any questions concerning these purchase orders. [Tr. 1120-1136; Govt. Exh. 44].

32. As a general matter, Dr. C. Chein credibly testified that she would not give estrogen to a female patient who had had breast cancer because it is a contraindication: "it causes the cancer to grow." [Tr. 1159-1160, 1162-1163, 1166; Govt. Exh. 95 at 46].

(3) *Respondent's U.S. Patients*

33. The Respondent conducts physical examinations of his U.S. patients who come to his office, prior to dispensing controlled substances. [Tr. 1399]. His initial patient evaluations take approximately four hours. [Tr. 1633]. The Respondent also trains other physicians, including doctors from overseas, on his treatment protocol. [Tr. 1633-1636]. Some doctors are also the Respondent's patients. [Tr. 1641].

(a) *Mr. Marshall Gilbert*

34. Mr. Marshall Gilbert ("Mr. Gilbert") credibly testified that he became the Respondent's patient in 1998. At that time, he was "morbidly obese," had a "high liver count," and he "just wasn't feeling well." [Tr. 1609]. Mr. Gilbert's health improved under the Respondent's care. [Tr. 1609-1610]. He subsequently referred his wife as a patient to the Respondent. [Tr. 1610].

35. Mr. Gilbert began working as an independent contractor for PSLEI in 1998. He provided consulting services as a business administrator. [Tr. 1610, 1632, 1676]. In 1999, Mr. Gilbert began working out of an office at PSLEI. [Tr. 1727]. Among other activities, Mr. Gilbert views his responsibilities to PSLEI as ensuring PSLEI's personnel comply with law enforcement requests. [Tr. 1652-1657, 1671-1673].

36. In 2001, Mr. Gilbert recommended that PSLEI hire a pharmacist-consultant to ensure the company's employees were handling pharmaceutical products consistent with pharmacy standards. The consultant worked at PSLEI for approximately 60 days. [Tr. 1649-1651]. This consultant also ensured that PSLEI's computer program, MicroPharmacy, was in place and operating properly. [Tr. 1650].

37. To the best of Mr. Gilbert's recollection, the Respondent has never had an adverse patient claim filed against him. [Tr. 1642].

(b) *Mr. Robert Jones*

38. Mr. Robert Jones has been a patient of the Respondent's since 1994. He credibly testified at the hearing about the effect of the Respondent's regimen upon him. [Tr. 1949-2021]. Specifically, Mr. Jones testified that, after following the Respondent's treatment regimen for seven or eight months, his primary care doctor advised him he could stop taking his high blood pressure medication. He had been taking such medication for over 25 years. [Tr. 1952-1953]. Further, Mr. Jones' cholesterol went from over 200 to 155, where it has remained. [Tr. 1953]. He also credibly testified that he has experienced increased energy. [Tr. 1953-1954]. Mr. Jones believes the Respondent's hormone replenishment therapy improved the quality of his life. [Tr. 1955-1956]. He also believes he experienced no negative side effects from this treatment. [Tr. 1964-1965].

39. From 1994 to 2002, Mr. Jones was also a marketing consultant and spokesperson for the Respondent. He spoke on behalf of the Respondent and his treatment regimen across the United States and overseas. [Tr. 1955-1956, 1986]. However, in September of 2001, Mr. Jones had an altercation with Dr. Daryl Garber, and Mr. Jones ceased working at PSLEI. [Tr. 1996-2005].

(4) *The Respondent's Patents*

40. Mr. Thomas Babbit is an attorney who represented the Respondent in obtaining patents on his medical procedure. [Tr. 1854, 1865]. He has represented the Respondent since 1996. [Tr. 1899]. The Respondent applied for and was granted patents in the United Kingdom, [Tr. 1860; Resp. Exh. 1007], and in the United States [Tr. 1861; Resp. Exh. 1016]. On January 5, 1999, the Respondent was issued a U.S. patent on his total hormone replacement therapy practice. [Tr. 1042, 1865-1866; Resp. Exh. 1017]. He was also issued a patent for hormone replenishment therapy, from the United Kingdom, which was to be enforced in Hong Kong. [Tr. 1881-1882; Resp. Exh. 1007].

41. In December of 2002, the Respondent also applied for a patent on his testosterone composition. [Tr. 1861; Resp. Exh. 1016]. The Respondent compounded this substance to obtain a more precise dosage. [Tr. 1889-1895; Resp. Exh. 1016].

42. Mr. Babbit credibly explained that the Respondent has three patentable inventions: first, combining multiple hormones for a treatment regimen; second, the hormone levels to set as a standard for this regimen; and third, setting the level and timing of the administration of human growth hormone. [Tr. 1874-1875, 1906-1907; Resp. Exh. 1017].

43. The issuance of patents confirms the originality of the inventions. [Tr. 1880]. However, the patent office would not necessarily examine the safety of a product as part of the patentability investigation of the invention. [Tr. 1936-1937, 1941]. Specifically, the patent office guidance regarding safety of an invention of medical treatment states: "Thus, while an applicant may on occasion need to provide evidence to show that an invention will work as claimed, it is improper for any patent office personnel to request evidence of safety in the treatment of humans or regarding *degree* of effectiveness." [Tr. 1937; *see also* Tr. 1941; Govt. Exh. 138 at 4].

44. The Respondent also applied, and a patent was issued, for his treatment of multiple sclerosis patients with hormone replenishment therapy. [Tr. 1896-1898; Resp. Exh. 1044].

45. Other governments have also issued the Respondent patents, to include the People's Republic of China. [Tr. 1884]. The Respondent also licenses others to practice the procedures covered by his patents, including overseas practitioners. [Tr. 1043].

(5) *Investigation of the Respondent*

46. The Respondent submitted an application dated July 20, 2000, to renew his DEA registration. [Govt. Exh. 1]. On the application, the Respondent answered "yes" to the question asking whether he had ever had a state professional license or controlled substance registration revoked, suspended, denied, restricted, or placed on probation ("liability question"). [Govt. Exh. 1 at 2]. That answer triggered a routine DEA investigation, and Diversion Investigator Doris DeSantis was assigned the case. [Tr. 214-216]. The Respondent's DEA registration number is AC1643661. [Tr. 219; Govt. Exh. 2].

47. DI DeSantis retrieved documents related to the Respondent's answer to the liability question, to include an internet database check from the California Medical Board, [Govt. Exh. 3], an Arrest and Booking Form from the City of Beverly Hills, [Govt. Exh. 30], and a record from the Superior Court of California, County of Los Angeles, ("Superior Court"). [Govt. Exh. 33; *see also* Tr. 220-31].

48. In 1994, the Respondent was charged with perjury before the California Superior Court. In a jury trial in 1996, the Respondent was found guilty of three counts of criminal perjury. [Govt. Exh. 33 at 1-4]. He was sentenced to three years of probation, 30 days of incarceration on weekends, $1,000 restitution, and 1,000 hours of community service. [Tr. 228-229; Govt. Exh. 33 at 5]. However, the Respondent filed a petition for habeas corpus relief in federal district

court. The district court denied his petition, and he appealed that denial to the Ninth Circuit Court. In June of 2004, the Ninth Circuit, deciding the case en banc, reversed the district court's decision, concluding: "As there was insufficient evidence under *Jackson* to sustain any of Chein's three counts of [perjury] conviction, the district court erred in denying habeas relief." *Chein v. Shumsky, et. al.*, 373 F.3d 978 (9th Cir. 2004).

49. Effective June 30, 1995, the Division of Medical Quality, Medical Board of California ("Medical Board") adopted and ordered enforced a Stipulated Settlement and Decision, wherein the Respondent was disciplined for engaging in false advertising and failing to obtain a fictitious-name permit. [Govt. Exh. 114 at 4, 11]. The Medical Board revoked the Respondent's medical license, stayed the revocation, and placed the Respondent on probation for three years, with various terms and conditions. [Tr. 232-239; Govt. Exh. 114 at 5-9].

50. Effective February 18, 2000, the Medical Board again acted, adopting as its decision a proposed decision of an Administrative Law Judge ("ALJ"), finding that the Respondent had violated various California laws, to include "Prescribing Without Medical Indication," "Incompetence," "Repeated Negligent Acts," and "Failure to Maintain Adequate and Accurate Records." [Govt. Exh. 4 at 32, 58-59]. The ALJ's decision also found that the Respondent had engaged in false or misleading advertising [Govt. Exh. 4 at 59-61], and "excessively treating or using

diagnostic procedures" [Govt. Exh. 4 at 61-62] by placing a laboratory order form on the Respondent's web site. The ALJ and the Medical Board subsequently revoked the Respondent's medical license. [Govt. Exh. 4 at 67].

51. However, by a Ruling on Submitted Matters, the Superior Court of California, County of Sacramento, ordered the Medical Board to set aside its decision of February 18, 2000, and to conduct further proceedings. [Govt. Exh. 4 at 5-21, 25-26, 29-30]. In response, on January 4, 2001, the Medical Board vacated and set aside its decision and remanded the action to the administrative law judge for further proceedings. [Govt. Exh. 4].

52. During the Medical Board's revocation period in 2000, PSLEI was owned by Dr. Connie Chein and operated by Dr. Darryl Garber. [Tr. 1050]. Yet the record demonstrates that the Respondent dispensed controlled substances from PSLEI during the Medical Board's revocation period. Specifically, a document dated February 29, 2000, from the Respondent to an employee, indicates he told the employee to ship controlled substances to a clinic overseas for a patient. [Tr. 827-829; Govt. Exh. 105 at 36, 45-46].

53. Further, on August 11, 2000, the Respondent, without a DEA registration entitling him to so act, sent controlled substances from PSLEI, International Division, in Salt Lake City, Utah, to Japan. [Tr. 829-831; Govt. Exh. 105 at 39-42].

54. By a Decision dated February 27, 2002, the Medical Board entered into a Stipulated Settlement and Disciplinary Order with the Respondent. [Tr. 258-259; Govt. Exh. 113; *see also* Govt. Exh. 125]. The Medical Board ordered, effective March 29, 2002, that the Respondent's medical license be revoked, but that the revocation be stayed and the Respondent be placed on probation pending completion of specified terms and conditions. [Govt. Exh. 113 at 5-6]. The terms included completion of a physician assessment and clinical education, and he was to obey all federal and state laws. [Govt. Exh. 113 at 5-6].

55. In August of 2002, the Medical Board filed an Accusation, asserting that the Respondent engaged in gross negligence in his treatment of a patient. [Govt. Exh. 124 at 7-9]. Further, the Medical Board accused the Respondent of repeated negligent acts in treating this patient, of incompetence in treating this patient, of prescribing without medical indication, and of maintaining inadequate records. [Govt. Exh. 124 at 9-13]. The Medical Board also accused the Respondent of engaging in gross negligence, repeated negligent acts, and incompetence, and in prescribing without medical indication and maintaining inadequate records in the treatment of a second named patient. [Govt. Exh. 124 at 13-17]. Lastly, the Medical Board accused the Respondent of general unprofessional conduct, of the unlicensed practice of medicine, of dishonesty, of obtaining and dispensing controlled substances unlawfully, of failing to comply with federal laws regarding controlled

substances, and of failing to maintain adequate and accurate records. [Govt. Exh. 124 at 17-19]. This matter was still pending as of the time the record was closed in this proceeding.

(6) *DEA Investigations*

56. As an earlier part of DEA's involvement, the record discloses that U.S. Magistrate Judge Wistrich, Central District of California, issued a search warrant, dated May 23, 1996, for the Respondent's registered location. [Tr.128; Govt. Exh. 35 at 2-3]. DEA diversion investigators participated in the execution of this search warrant, and two controlled substances, both anabolic steroids, were seized. [Tr. 129-132]. No records pertaining to these controlled substances were found or seized at PSLEI. [Tr. 130, 134]. For example, no inventory records, purchase records, or distribution records were located or seized that day. [Tr. 154, 180-82]. However, patient records and computer hardware and software were seized. [Tr. 151-152; Govt. Exh. 35 at 56-57]. The record is unclear concerning what action, if any, DEA took in response to the information received pursuant to this search.

57. Further investigation revealed that, between January 1, 1995, and June 3, 1996, the Respondent had received controlled substances, to include testosterone, from a distributor, Henry Schein, Inc. [Tr. 135; Govt. Exh. 36]. Effective February 27, 1991, anabolic steroids became Schedule III controlled substances. [Govt. Exh. 42]. Testosterone is

a hormonal substance included as an anabolic steroid under DEA regulations. [Govt. Exh. 42 at 4-5].

58. Diversion Investigator ("DI") Robert Brasich credibly testified that in 1994 he had been contacted by an FDA investigator to assist in an FDA investigation of PSLEI. [Tr. 118]. The FDA had conducted two undercover meetings with the Respondent. [Tr. 120]. During one such meeting in October of 1994, an FDA investigator had told the Respondent that he had an injured disc, and that he wanted to build up some muscle mass. [Tr. 121]. Dr. Chein took a baseline hormone blood test. [Tr. 144-45]. This investigator received a prescription for testosterone gel, a Schedule III controlled substance, and human growth hormones, also controlled substances. [Tr. 121; Govt. Exh. 35 at 24-28].

59. Customs Special Agent ("SA") Gary Phillips also participated in an undercover meeting with Dr. Chein. In March of 1995, SA Phillips told Dr. Chein that he was a power lifter, used anabolic steroids, and competed. He said he wanted to obtain human growth hormones for gaining strength for power-lifting competitions. The Respondent offered to mail SA Phillips human growth hormones on a weekly basis. [Govt. Exh. 35 at 33-34]. Dr. Chein also took a baseline hormone blood test. [Tr. 144-45]. Concerning detection of anabolic steroid use during competitions, the Respondent advised SA Phillips to cease using the steroids a couple of days before the competition, so that the steroids would not be detected in a drug test. [Tr.122].

60. In July of 1995, DEA SA David Garcia, a competitive power lifter, met Dr. Chein and told him he was trying out for the Olympic team. [Tr.124; Govt. Exh. 35 at 35]. Dr. Chein noted that SA Garcia's testosterone level might be low, [Tr. 124, 142], and he recommended that SA Garcia use steroids and advised him to cease using the drug a few days before the competition. [Tr. 125]. A blood test was taken at this visit. [Tr. 125-126, 143]. Dr. Chein gave SA Garcia a prescription for testosterone gel, a Schedule III controlled substance, and gave him human growth hormone. [Tr. 126, 183]. Between July 26 and August 23, 1995, SA Garcia received five vials of human growth hormone. On or about September 9, 1995, SA Garcia received filled prescriptions of testosterone gel. [Govt. Exh. 35 at 35-38].

(7) *The Respondent's Records*

61. On January 31, 2001, DI DeSantis issued a Notice of Inspection to the Respondent's clinic. [Tr. 867; Govt. Exh. 5]. However, Dr. Chein was not present when DI DeSantis arrived at the clinic. [Tr. 264]. The purpose of the inspection was to interview Dr. Chein and to inspect his recordkeeping. [Tr. 263]. In the absence of the Respondent, DI DeSantis requested that the Respondent's associate, Dr. Garber, produce invoices for purchases of controlled substances, inventory documents, and dispensing logs. [Tr. 268-69]. Dr. Garber only provided DI DeSantis with two invoices for controlled substances during this visit. [Tr. 275; Govt. Exh. 6].

62. A staff member informed DI DeSantis that additional invoices were not available because they were off-site at an accountant's office. [Tr. 273]. Further, the inventory documents and dispensing logs were unavailable because they were contained in a new computer system and no one at the clinic knew how to access the documents. [Tr. 269, 273-74].

63. DI DeSantis informed Dr. Garber that it was a violation of DEA regulations to keep invoices for controlled substances off-site, for the invoices should be kept at the clinic, the registered business location. [Tr. 274, 277]. Further, she informed him that the other required records should be "readily retrieval" [sic] for DEA's inspection and copying, and failing to keep the records in this manner was also a violation of the DEA's regulations. [Tr. 274, 870-871].

64. Relevant to the January 31, 2001 time-frame, DEA registrants who are physicians dispensing controlled substances must maintain an inventory of controlled substances on hand at the dispensing location. [Tr. 203]. This inventory would consist of an initial inventory when the registrant first opened for business. After this initial inventory, registrants need to conduct a manual inventory of all controlled substances on hand at that place of business every two years thereafter. [Tr. 205]. Each such record must be maintained for two years. [Tr. 205-06].

65. Inventory records for a dispenser of controlled substances must be readily retrievable, which

means that "if the DEA . . . investigators would go to the physician's office we would ask him to see his biennial inventory. He should be able to produce it within regular working business hours." [Tr. 207].

66. A dispensing physician must also keep a dispensing log of all controlled substances dispensed to patients. This log should have the patient's name, address, the name of the drug the patient received, how much of the drug, the date it was dispensed, and the name of the person who dispensed the drug. This log should be maintained for two years. [Tr. 208].

67. A registrant is also required to file a report with the DEA if they had any theft or loss of controlled substances. [Tr. 209].

68. A registrant must also keep purchase records for the controlled substances purchased. [Tr. 209]. The registrant is required to keep the invoices from the supplier of these purchased controlled substances. [Tr. 209-210].

69. At this visit and the subsequent visit in February of 2001, DI DeSantis did not receive a biennial inventory report. [Tr. 1242].

70. On February 5, 2001, DI DeSantis returned to the Respondent's clinic. [Tr. 892]. The Respondent was not present. DI DeSantis told his associate, Dr. Garber, that she had returned to retrieve the records requested in January. [Tr. 277-279]. Dr. Garber provided some records, to include a one page "Inventory Report" dated February 5, 2001, and dispensing

logs organized by product. DI DeSantis also received four invoices for phentermine, a controlled substance. [Tr. 331-333; Govt. Exh. 17(a)-17(d)]. Although DI DeSantis had requested access to all invoices of controlled substances received at the clinic, these were the only invoice documents she was provided. [Tr. 333-34]. Although she waited two to three hours DI DeSantis was not provided any other records at that time. [Tr. 280-284; Govt. Exh. 8, 9-16].

71. She did not receive any invoices concerning the purchase of testosterone. [Tr. 334].

72. The dispensing logs documented the dispensing of phentermine and testosterone. [Tr. 285, 333-334]. However, these documents were incomplete. [Tr. 281-292, 299-316; Govt. Exhs. 10 and 11]. They failed to document the name of the doctor authorizing the dispensing of the controlled substances. [Govt. Exhs. 9-16]. Further, the dispensing logs indicated that controlled substances were dispensed to patients residing overseas. [Govt. Exhs. 10, 11, 12, 15, 16; Tr. 292-298, 299-301, 302-306, 309-311, 311-315]. Specifically, from July of 2000 to February of 2001, controlled substances were dispensed 317 times to individuals in 11 different countries. [Govt. Exh. 46; Tr. 316-319].

73. PSLEI's records indicate that Dr. C. Chein's DEA Registration number was used to order controlled substances that were then shipped to PSLEI. [Tr. 1487-1492; Govt. Exh. 45]. Specifically, the DEA Certificate of Registration number listed on these

invoices belongs to Dr. Connie Chein, the sister of the Respondent in this case. [Tr. 335-339, 643; Govt. Exh. 27]. Dr. Connie Chein's registered location is in Beverly Hills, California, not at the Respondent's clinic. [Tr. 338; Govt. Exh. 27]. However, the invoices indicated that the controlled substances ordered under Dr. Connie Chein's DEA Certificate of Registration were actually delivered to the Respondent's clinic in Palm Springs, California. [Govt. Exh. 17(a)-17(d); Tr. 335].

74. Further, in August and November of 2000, distributors of controlled substances shipped testosterone to Dr. Connie Chein at PSLEI. [Tr. 532-533, 625-628, 630; Govt. Exhs. 20(j), 44(c), 44(f), 44(g), 44(i), 44(l) and 44(m)]. Although on November 21, 2000, Dr. Connie Chein was the owner of PSLEI, her DEA registered location was in Beverly Hills, California, not at PSLEI. [Govt. Exh. 44(a) at 3; Tr. 532-533]. Additionally, when asked by DI DeSantis for a copy of the ownership transfer documents, Dr. Connie Chein was unable to produce them. [Tr. 643-644]. Further, Dr. Connie Chein stated that she had only been out to PSLEI in Palm Springs once in five years. [Tr. 645; Govt. Exh. 28 at 14]. Further, Dr. Connie Chein had not given PSLEI or Dr. Edmund Chein permission to use her DEA registration to order controlled substances for use at PSLEI. [Govt. Exh. 28 at 15-16; Tr. 646-647].

75. However, in a patient file, a document dated November 16, 2000, and labeled "Palm Springs Life Extension Institute, Utah, Connie Chein, M.D.,"

indicates that a controlled substance, testosterone, had been ordered for the patient. The form lists Connie Chein's DEA number and her California Medical License. [Govt. Exh. 95 at 45; Tr. 653-655].

76. Dr. Darryl Garber also possesses a DEA Certificate of Registration, and prior to February 16, 2001, his registered location was his home address in Rancho Mirage, California. [Tr. 518-519]. On February 12, 2001, Dr. Garber's registered location was transferred to the Palm Springs Life Extension Institute ("PSLEI") at a Palm Springs, California, address. [Govt. Exhs. 32, and 43 at 13; Tr. 340-341, 539]. Multiple DEA registrations at the same address are not a problem, provided the individual registrants maintain separate dispensing and purchasing records. [Tr. 341].

77. Yet the DEA received copies of distributors' invoices dated after February 12, 2001, showing controlled substances were purchased by PSLEI, but shipped to the Rancho Mirage, California, home address of Dr. Garber. [Tr. 525-529; Govt. Exh. 20(c), 20(d)].

(8) *DEA's Management Conference*

78. On August 23, 2001, DI DeSantis and DI Willmont met with the Respondent at PSLEI to provide him with information during a management conference following the DEA inspection in January of 2001. [Tr. 546]. Specifically, the purpose of the conference was to provide the Respondent with

information concerning any violations the DEA representatives found during the inspection. [Tr. 546-547]. DI DeSantis informed the Respondent that the primary problems identified during the inspection involved (1) the lack of readily retrievable inventory records, (2) the lack of biennial inventory records, and (3) the dispensing of controlled substances overseas without a DEA registration authorizing such activities. [Tr. 547-548, 559, 1242-1243, 1245]. Dr. Chein was also informed that he needed an exporter's registration to ship controlled substances overseas. [Tr. 548, 582, 1245-1246; Govt. Exhs. 23, 24, 39].

79. At that meeting, the Respondent produced the faxed copy of the regulations DI DeSantis had faxed to Dr. Garber. [Tr. 548; Govt. Exh. 19]. The Respondent referred to these regulations and explained that he did not need an exporter's registration because he fell under the exception found in 21 United States Code 953(a)(4).[2] [Tr. 551-552]. DI DeSantis informed the Respondent that, even if this section applied to the Respondent, he would need exporter permits to ship the controlled substances overseas. [Tr. 553; Govt. Exh. 23]. The Respondent admitted that he did not have such permits. [Tr. 553].

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[2] Although DI DeSantis testified to a citation of 21 C.F.R. 953, I find the record supports that she was actually referring to 21 U.S.C. 953(a)(4). This section refers to narcotic controlled substances. Phentermine and testosterone are not narcotic drugs. [Tr. 555]. The appropriate section of the law dealing with these substances would be 21 U.S.C. 953(e).

80. The Respondent also told DI DeSantis that he was shipping controlled substances overseas to doctors. [Tr. 554; Govt. Exh. 25]. These overseas doctors would then dispense the controlled substances to their patients. [Tr. 554-555]. DI DeSantis again told the Respondent that, even under those circumstances, he would need a permit to export controlled substances to these doctors. [Tr. 556].

81. Despite DI DeSantis' information to Dr. Chein, he continued to export controlled substances without obtaining any additional registrations or permits from the DEA. [Tr. 557-558]. He stated that he would continue to do so until he received something in writing from the DEA. Dr. Chein also refused to tell the DEA investigators the methods he used to export controlled substances. [Tr. 558-559].

82. At the conclusion of the management conference, the Respondent provided the DEA diversion investigators with invoices for controlled substances. [Tr. 560; Govt. Exhs. 21 and 22]. The two invoices, one from Spectrum and one from Pharmacia & Upjohn, indicated that testosterone was sold to PSLEI in Palm Springs, California, and the product was shipped on March 13, 2001, to Dr. Garber at his Rancho Mirage, California location. [Tr. 571; Govt. Exh. 21 at 2]. Neither invoice contained a DEA registration number. [Govt. Exh. 21; Tr. 570-571]. During this time, the Respondent was the owner of PSLEI. [Tr. 971].

(9) *Administrative Inspection of March 13, 2002*

83. On March 13, 2002, DI DeSantis and others from the IDEA executed an administrative inspection warrant at PSLEI. [Govt. Exh. 82; Tr. 757-758]. The DEA sought to review foreign patient files, invoices, documents pertaining to inventories of controlled substances, and controlled substances dispensing logs. [Tr. 759]. Although DI DeSantis requested documents pertaining to a biennial inventory, no such documents were provided. [Tr. 760].

84. DI DeSantis asked Dr. Garber to identify foreign patient medical records. Under the authority of this warrant, the IDEA seized a representative sampling of these medical files. [Tr. 925-927].

(10) *October 2002 Search of PSLEI*

85. In October of 2002, DI DeSantis participated in the execution of a search warrant at PSLEI. [Tr. 836]. She seized a product marked "adrenal extract." She had this product analyzed at a DEA laboratory, and the laboratory identified the product as phentermine. [Tr. 836-837; Govt. Exh. 135].

86. DI DeSantis also seized documents that identified sales of controlled substances to the Respondent's overseas patients. [Tr. 838-842; Govt. Exh. 136]. These sales took place in September of 2002.

87. DI DeSantis also seized a memorandum from PSLEI's records from the Respondent to his

staff. In this memorandum, he directs his staff not to send medicines to a patient in Japan at a business address, because the patient would have to pay taxes on the substances if they were shipped to that location. [Tr. 842-843; Govt. Exh. 136 at 10]. A facsimile cover sheet was also seized, documenting that a staff member had shipped four packages of human growth hormone. The document also recorded: "The packages were shipped at no value and indicating business documents as being shipped." [Govt. Exh. 136 at 17].

88. DI DeSantis also seized a Nevada driver's license during a search of the Respondent's home. Although the driver's license had the Respondent's picture on it, the name on the driver's license was "Ben Young." [Tr. 851-852; Govt. Exh. 137].

(11) *Serving the Order to Show Cause and the Immediate Suspension*

89. When DI DeSantis, with other DEA personnel, served the Order to Show Cause and Immediate Suspension on November 12, 2001, the Respondent was not available at PSLEI. [Tr. 593]. When DI DeSantis asked for the Respondent's DEA Certificate of Registration, she was told that the document could not be located. [Tr. 591-593]. She also requested the controlled substances on the premises, for she would need to impound them because of the immediate suspension. [Tr. 593]. Dr. Garber told the investigators that the Respondent did not have any controlled substances at the registered location. Further, he

stated that any controlled substances found in the clinic belonged to him. [Tr. 593].

90. Once again DI DeSantis was provided invoices. [Tr. 595; Govt. Exh. 45]. She called her DEA office and determined that the DEA registration number AC7093292, on the first invoice, belonged to Dr. Connie Chein. [Tr. 596; Govt. Exh. 45(a)]. These controlled substances were shipped on or about March 26, 2001, and received at PSLEI on or about March 30, 2001. [Tr. 598; Govt. Exh. 45(a)].

91. The next three invoices document that shipments of testosterone were sold to PSLEI, but shipped to Dr. Garber's Rancho Mirage address in February and March of 2001. [Govt. Exh. 45(b), (c), and (d)]. As of these dates, the Respondent was the owner of PSLEI. [Tr. 599-602]. Two of these invoices do not have a DEA registration number listed [Govt. Exh. 45(b) and (c); Tr. 598-600], and the third invoice has the Respondent's DEA registration number listed [Govt. Exh. 45(d); Tr. 601]. A fourth invoice also documents that testosterone was ordered and shipped to Dr. Garber at Rancho Mirage in March of 2001. [Govt. Exh. 45(g)]. No DEA registration number appears on this invoice, but during this time frame, the Respondent owned PSLEI. [Tr. 604-605].

92. Another invoice reflects that, in November of 2000, Dr. Garber purchased testosterone, and had the controlled substance delivered to his home address. [Govt. Exh. 45(e); Tr. 602]. At that time, Dr. Connie Chein owned PSLEI. [Tr. 603].

93. Also in November of 2000, testosterone was purchased by Dr. Connie Chein, her DEA number appeared on the invoice, and the controlled substance was delivered to PSLEI in Palm Springs, California. [Govt. Exh. 45(f); Tr. 603-604]. However, Dr. Connie Chein has never been registered to dispense controlled substances at that address. [Tr. 609; Govt. Exh. 50]. Rather, her DEA registered location is in Beverly Hills, California. [Govt. Exh. 43 at 8].

94. DI DeSantis also received PSLEI's dispensing logs. [Govt. Exhs. 84, 85, 86, 87, 88, 89, 126, 127, 133, 134; Tr. 764-765, 773-799]. The logs indicate that controlled substances were dispensed to patients outside of the United States, and the doctor listed on the logs was either the Respondent or Dr. Darryl Garber. [Govt. Exhs. 84, 85, 86, 87, 88, 89, 126, 127, 133, 134; Tr. 766-768, 773-799].[3]

95. DI DeSantis also obtained about 100 patient files for overseas patients. [Tr. 811]. Approximately twenty-one of these files were randomly selected by a DEA administrative support employee and were given to Doctor Zipser for analysis. [Govt. Exhs. 91-111; Tr. 811-812].

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[3] For this proceeding, the dispensing log transactions were organized in a chart and on a spread sheet for ease of analysis, sorting the information by patient name and by dispensing date. [Govt. Exhs. 128, 129; Tr 800-802, 805].

(12) *Dr. Zipser's Analysis of the Respondent's Medical Practices*

96. Dr. Robert Zipser credibly testified for the Government as an expert in the field of internal medicine and endocrinology. [Tr. 497; Govt. Exh. 115]. Endocrinology is "the study of glands and hormones." [Tr. 364]. Dr. Zipser has a license to practice medicine in California, has a DEA Certificate of Registration, and is board certified by the American Board of Internal Medicine in the subspecialties of endocrinology, metabolism, and gastroenterology. [Tr. 371, 375-76]. Dr. Zipser also conducted clinical research on the metabolism of adrenal steroids. [Tr. 370].

97. As part of his training, Dr. Zipser learned that the methodology to use in treating patients was to take a history from the patient, conduct a physical examination, formulate the appropriate diagnosis, and then develop a treatment plan based on this information. [Tr. 373].[4] This methodology is generally accepted within the medical community nation-wide. [Tr. 391-92].

98. Dr. Zipser has some patients who reside in foreign countries. However, he credibly testified that he is not usually directly involved in their care unless they are in the United States. These patients return periodically to the United States for treatment by Dr. Zipser. [Tr. 439]. Generally, Dr. Zipser did not interact

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[4] Throughout the transcript this methodology is often referred to as a "scientific methodology." [*See, i.e* Tr. 373].

with their physicians in the foreign countries. [Tr. 438].

99. On cross-examination, Dr. Zipser was asked about deviation from the standard of care when a physician performed the role of actually treating a patient versus the physician performing the role of advisor to the treating physician. Dr. Zipser credibly noted:

> If a doctor in Japan is asking for some advice on the doctor in Japan's care of a patient that is . . . not any kind of deviation.
>
> If the doctor in Palm Springs is writing prescriptions, sending medication, and directing the care himself – that is, he is actually treating the patient, then I definitely have a problem. Because the one who is actually treating the patient by giving the medication – sending it from his own facility, writing the prescriptions, he is not the physician – or a physician of record.

[Tr. 2655].

100. Dr. Zipser made a distinction regarding the standard of care and the role of the physician in the treatment of a patient. Again, he credibly testified:

> The distinction is if you look at a CT scan from a doctor in South Carolina . . . and that doctor asked you to give your advice and you give your advice, you may still have a medical-legal issue there if your advice is bad. But in terms of standard of care, you are not

> taking primary care of the patient. You are not examining. You are not . . . prescribing to the patient. You are giving advice to a physician.
>
> In this case[,] the records appear to show that the patient was directly advised by the physician and that the medication was – and prescriptions were written by the physician. And even at – at least in some of these patients, presumably all, that the medication was actually even shipped from the physician's office in California.
>
> I think there is quite a distinction between having an international expert – not even an international expert give advice to a physician, 'What do you think of this x-ray' or 'How do you treat,' and having that same physician prescribe the medication, write the prescriptions, send the drugs, communicate with the patient.

[Tr. 2661-2662].

101. Dr. Zipser also received training and served as a medical reviewer for the California Medical Board. [Tr. 382]. As a reviewer, he would review medical records to determine "whether the quality of care provided by a physician is within the standard of [care within] the community, that is, the standard that a reasonable person would expect from a physician of similar qualifications and training." [Tr. 382-83]. He actually served as a reviewer between 12 and 18 times. [Tr. 382-84].

102. The general standard of care or obligations of a physician would include taking a patient's history, conducting a physical examination and any needed diagnostic tests, arriving at an appropriate therapy or plan of action, and implementing the treatment. [Tr. 435]. This methodology is the same for all physicians. [Tr. 436-437]. However, the follow-up examination process is usually problem-oriented. "That is, emphasis is placed on the current problems." [Tr. 2599].

103. Dr. Zipser credibly testified that there are different gradations in terms of a deviation from the standard of care. Specifically, there is a simple deviation from the standard of care at one end of the spectrum, and an extreme departure from the standard of care at the other end of the spectrum. Further, there are "other sub qualifications, including a lack of knowledge, [and an] inappropriate use of drugs." [Tr. 383].

104. Dr. Zipser credibly testified that he knows of most of the physicians practicing endocrinology in the southern California community. He stated that he knows physicians that give individual hormones because they feel their patients may have hormonal deficiencies, but he did not "know anyone else [besides Respondent] that gives this kind of multiple hormone replacement." [Tr. 417-418, 420-422]. Further, the concept of giving patients multiple hormones to bring their hormonal levels up to the level of a twenty year old is not a topic found in the mainstream medical literature. [Tr. 422-423]. However,

Dr. Zipser did review a book and an article written by the Respondent. [Tr. 426].

105. Prior to prescribing testosterone for a patient, Dr. Zipser takes a blood test to determine the patient's current testosterone level. If he decides the patient would benefit from testosterone replacement therapy, he prescribes the standard replacement doses either recommended by the manufacturer or by the Physician's Desk Reference. [Tr. 429-432]. His prescribing is to address a deficiency in the hormone level of a specific patient. [Tr. 434-435]. To determine a deficiency, Dr. Zipser would compare the patient's hormone level with an established, published norm. [Tr. 435].

106. Dr. Zipser credibly testified about the side effects experienced from ingesting testosterone, which is a Schedule III controlled substance. Specifically, these side effects include aggressive behavior, acne and other skin changes, swelling of the breasts, some liver disease, and possibly promoting growth of prostate cancer. [Tr. 386-87, 401]. The use of anabolic steroids may be contraindicated when a patient has or had prostatic cancer or had some type of psychological disorder that may be aggravated by the aggressive behavior side effect. [Tr. 387-88].

107. Dr. Zipser credibly testified that, when he reviewed the Respondent's patients' charts, he interpreted any reference to "adrenal extract" to mean the controlled substance phentermine. [Tr. 2430]. He also credibly testified about the effects experienced by the

ingestion of phentermine, including speeding up of metabolism and heart rate, decrease in appetite, and increase in blood pressure. [Tr. 388-89]. According to Dr. Zipser, ingestion of phentermine would be contraindicated in a patient with hypertension, with underlying cardiac disease, and patients susceptible to pulmonary hypertension. [Tr. 389-90]. For a physician to continue to dispense phentermine to a patient, he or she "must have close follow-up with patients receiving phentermine because of the potential side effects . . . That follow-up may include EKGs and certainly includes serial blood pressure, pulse reading, and obtaining history and physical examination." [Tr. 390].

108. At the request of Government Counsel, Dr. Zipser reviewed twenty-one medical records for Respondent's patients. He did not examine or otherwise interact personally with the patients. The scope of his review was as follows:

> The medical records were reviewed using the guidelines for Expert Medical Review provided by the Medical Board of California. The medical records are analyzed to determine if patient care is within the standard of care for physicians of similar training. These criteria include appropriateness and thoroughness of medical history and physical examinations, appropriate and legible documentation in the medical records, appropriate medical treatment and patient follow up. Evaluation of physician prescribing medications includes appropriateness of indications

> and the choice of medication, appropriate laboratory or other diagnostic testing for the medication prescribed, and appropriate follow up and documentation. Based on the information provided in each patient's medical record the actions of the physician are determined to be within the standard of care, a simple departure from the standard of care, or an extreme departure [from] the standard of care. The aggregate care of all patients reviewed are than assessed to determine if the total actions of the physician represent a departure from the standard of care. For this review, the medical records were examined solely in relation to administration of prescription medication.

[Govt. Exh. 112 at 2].

109. In the cover letter to his report, Dr. Zipser made the following general conclusion:

> As detailed in the following analyses, the medical records document multiple examples of extreme departure from the standard of medical care by Dr. Edmund Chein, Dr. Darryl L. Garber and the Palm Springs Life Extension Institute in the administration of prescription medications. These departures include administration of prescription medications without physical examinations, without appropriate medical testing, without proper indications, without follow-up visits, and often without any documentation that the prescribing physician had ever seen or examined the patient. These actions placed

> the patients at considerable risks of ill effects from these medications.

[Govt. Exh. 112 at 3].

110. Dr. Zipser concluded that the Respondent's medical care was an extreme departure from the standard of medical care in 20 out of the 21 patient records reviewed, and a departure from the standard of medical care in I out of the 21 patient records reviewed. [Govt. Exh. 112 at 4-12].

111. In the conclusion of his report, Dr. Zipser noted that "[s]everal indications of treatment listed by Dr. Chein and Dr. Garber for the prescriptions of these medications are not labeled indications or standard of care, including multiple hormones for 'reversing biological age,' phentermine for anxiety, and testosterone for atopic dermatitis." [Govt. Exh. 112 at 12].

112. Dr. Zipser's overall conclusion concerning Dr. Chein's prescribing practices in the 21 patient records reviewed was:

> The aggregate care of these twenty-one patients by Dr. Chein, Dr. Garber and the Palm Springs Life Extension Institute represents an extreme Departure from the standard of care primarily in the administration of prescription medications. The administration of estrogens to a patient with breast cancer and the administration of phentermine, sex hormones and thyroid in patients with hypertension, all without adequate physical

> examination or follow up examinations is a particularly dangerous and callous use of prescription medications. These deviations from the standard of care pose substantial risk of medication-induced ill effects on these patients, including risks of malignancy and cardiac disease.

[Govt. Exh. 112 at 12-13].

(13) *Dr. Rios' Analysis of the Respondent's Medical Practices and Disagreement with Dr. Zipser*

113. The Respondent's Counsel called Dr. David Rios, a physician who has practiced family medicine for twenty-five years and who provides his patients with primary care. [Tr. at 2694-2695]. He is Board certified in family practice. [Tr. 2819, 2839, 2880]. Dr. Rios credibly defined primary care as "the ongoing first contact with a patient dealing with their major ailments and complaints, dealing mainly with commonalities . . . generally, we'll work in conjunction with specialists in other areas to help manage those patients." [Tr. 2695]. He further explained that managed care has impacted the relationship between the primary care physician and the specialized physician, noting that "it's sort of fractionating so that there is now more separation of treatments." [Tr. at 2696].

114. Dr. Rios is also an active staff member at Saddleback Memorial Hospital in Laguna Hills, California. [Tr. 2710-2711]. In the 1980's he served as Chairman of the Department of Family Practice, and

he served on the hospital's credentials committee. [Tr. 2711].

115. Dr. Rios also served as a clinical investigator, working for Sandos Pharmaceuticals in studying the effects of a blood pressure medication in a private care setting. This study was subsequently published. [Tr. 2710].

116. Dr. Rios began attending conferences sponsored by the American Academy of Anti-Aging Medicine ["Academy"] in 1995. [Tr. at 2700-2701]. Anti-aging medical seminars are conducted in the U.S. and world-wide, to include Europe, Asia, and South America. [Tr. 2826, 2830]. Dr. Rios credibly defined "anti-aging medicine" as a form of medicine which tries to deal with preventing the diseases associated with aging. [Tr. 2879-2880].

117. Dr. Rios credibly testified that the Academy had 1,500 Academy-certified members, and that there were between 12,000 and 12,500 members who attend their conferences. [Tr. 2703, 2824-2827, 2829]. To become Academy certified, an applicant must (1) be board certified in another area of medical practice [Tr. 2821, 2829], (2) attend seminars approved by the Academy [Tr. 2822-2823], (3) pass a written-examination and an oral examination, (4) provide evidence of taking care of patients, demonstrating how the applicant manages anti-aging patients in the applicant's own practice, and (5) have patient records reviewed by the Academy. [Tr. at 2704, 2821-2825]. An applicant is also required to

complete approximately 100 hours of continuing education. [Tr. 2705]. In reviewing patient charts, the Academy looks to see "how you generally manage the whole concept" as opposed to one particular disease. [Tr. 2717-2718].

118. The Academy continues to serve as an educational focal point for world-wide practitioners to gather and discuss the continuing development of this medical practice. [Tr. 2709]. However, as of the date of the hearing, no medical insurance company, to include Medicare, covered the cost of anti-aging medical treatment, because it is not recognized as a disease process. [Tr. 2844-2845].

119. The practice of anti-aging medicine is not a medical specialty recognized by the American Board of Medical Specialties ("ABMS"). [Tr. 2818, 2821]. There is disagreement within the medical profession regarding the anti-aging medical practice. Dr. Rios credibly noted that "there are some traditional concepts that feel that medicine should only intervene when there is a disease process. And [anti-aging] medicine is not yet widely accepted, although I think that's changing." [Tr. 2880].

120. In Dr. Rios' case, the entire Academy certification process took approximately seven or eight years. [Tr. 2705]. Dr. Rios became Academy certified in anti-aging medicine at the beginning of 2003. [Tr. 2717]. The Academy does not recertify its members like the Board certification process in family practice medicine. Rather, Dr. Rios credibly

explained, "you just have to maintain membership in the society and attend conferences." [Tr. 2881]. The Academy is trying to get the ABMS to recognize anti-aging medicine as a subspecialty. [Tr. 2881-2882].

121. Dr. Rios had reviewed the California Medical Board's guidelines for expert reviewers, but he had never consulted with the Medical Board about these guidelines, had never consulted with the Medical Board about anti-aging medicine, and he had never testified before in a court proceeding concerning anti-aging medicine. [Tr. 2838-2839]. He has, however, been recognized as an expert witness in family practice medicine, and he has testified in that capacity at a court proceeding. [Tr. 2839].

122. Dr. Rios credibly testified concerning the differences in the use of hormone therapy between the practice of anti-aging medicine and traditional endocrinology. [Tr. 2711-2712]. Anti-aging medicine acknowledges that we age because our hormones decline. The philosophy is one of preventing disease or the progression of chronic diseases due to hormonal deficiencies, or "the reversing of the effects of other deficiencies before they become pathological." [Tr. 2713]. Traditional endocrinology focuses on treating disease "and all the protocols that are involved in treating an active deficiency or disease state." [Tr. 2712]. Further, the traditional endocrinologist is presented with a patient in a disease state, and then the endocrinologist "becomes the expert in treating that disease state." [Tr. 2712]. In anti-aging medicine, the physician will prescribe hormones to

get the patient's hormone levels "closer to what would be more becoming for, say, a 30 year old, as opposed to a 70 year old or 50 year old . . . The concept is the hormone levels being closer in a younger age group, you'll see more benefits of the anti-aging effects." [Tr. 2885]. Yet, Dr. Rios also credibly stated that the use of these hormone standards of a younger-aged group and the prescribing of hormones to meet these standards for an older patient, would be controversial within the medical community. [Tr. 2885].

123. A physician practicing anti-aging medicine relies upon extensive blood test results in determining what hormones to prescribe and in what strengths. [Tr. 2900-2929]. Dr. Rios credibly explained:

> Because most of the therapies are going to be based upon treating hormone levels that can't be measured accurately any other way. So that's the most critical piece of information in making a decision about the dosage, adjusting. The physical would be a small part, but it's traditionally done . . . The overwhelming amount of importance is the blood.

[Tr. 2900].

124. In discussing the adrenal hormones, Dr. Rios credibly explained that phentermine is a much milder version in terms of its pharmacology effects, to the adrenaline hormone. [Tr. 2799]. Thus, phentermine "is a synthetic version that is actually a milder

form of the adrenaline hormone." [Tr. 2799-2800]. Although phentermine has many uses, "its most commonly prescribed use is for suppression of appetite, weight loss, or an adjunct to be used in weight loss." [Tr. 2800, 2839-2841]. When prescribed for this purpose, Dr. Rios credibly asserted that continuity of care was the medical tradition or requirement regarding the appropriate follow-up monitoring of the patient. [Tr. 2842-2843]. Even when phentermine is prescribed for anti-aging purposes, the patient should still be seen and supervised while taking this medication. [Tr. 2843]. Yet Dr. Rios disagreed with Dr. Zipser's assumption that an EKG should be ordered and reviewed prior to prescribing phentermine. Rather, Dr. Rios credibly asserted:

> I don't believe it's necessary to do an EKG on every patient that goes on that particular medication. . . .
>
> An EKG is just a piece of – another factor of information that you arrive at using it, depending on what – your initial reason for prescribing it. And if you feel the patient has a contra-indication, he's having cardiac symptoms, something that would alarm you, then you would do an EKG to confirm or deny your [suspicions] . . . So you have to go by the risk factors.

[Tr. 2868-2869].

125. Dr. Rios credibly testified about what an examination should consist of prior to prescribing phentermine. [Tr. 2892-2894]. Specifically, Dr. Rios

affirmed that he would take a pertinent history, would conduct an examination, and would discuss options with the patient, assessing the risks versus the benefits of prescribing phentermine. [Tr. 2892]. Dr. Rios would collect this information contemporaneously with making his decision whether or not to prescribe phentermine for this patient. [Tr. 2893].

126. Concerning long-term prescribing of phentermine, Dr. Rios credibly testified that he had not seen a patient develop serious or major health consequences from taking phentermine for an extended period of time. [Tr. 2896]. Yet, phentermine can be overused so that the patient develops a tolerance to the drug. [Tr. 2896]. When used for weight loss, Dr. Rios prefers to use phentermine intermittently rather than for prolonged periods of time. [Tr. 2896]. Yet, he concludes that phentermine "can be used long term . . . safely." [Tr. 2897].

127. During his Academy board certification process, Dr. Rios became aware of Dr. Chein, for Dr. Chein was developing treatment protocols that were discussed at the academy's conferences. [Tr. 2706-2708]. Dr. Rios credibly testified that Dr. Chein was one of the early pioneers in this treatment area. [Tr. 2709]. Dr. Rios credibly testified that he did not have any reason to question the competence of Dr. Chein. [Tr. 2798].

128. In February or March of 2003, Dr. Rios began to work with Dr. Chein. [Tr. 2719, 2832]. Dr. Rios was an attending physician at the Palm Springs

Life Extension Institute one day per week, seeing patients with Dr. Chein. The rest of the time, Dr. Rios works at his regular family practice office. [Tr. 2720].

129. When questioned about recordkeeping at PSLEI, Dr. Rios observed that "everything is documented very thoroughly." [Tr. 2730]. Yet Dr. Rios was generally aware that primary care physicians do not always receive complete patient chart entries from specialists and vice versa, for such physicians select the documents they believe that the primary care physician needs to continue treating the patient. [Tr. 2875-2878].

130. At the hearing, Dr. Rios credibly explained a chart entry concerning the billing of services to one of Dr. Chein's patients. The chart entry reflected a bill in the amount of $2,110 for 12 weeks of therapy. [Resp. Exh. 1085 at 5]. Dr. Rios explained that that figure reflected the cost of the hormones and the cost to ship those hormones to Japan. [Tr. 2897-2898].

131. Dr. Rios was also aware that a testosterone gel was being compounded at the PSLEI and dispensed there to patients of the clinic. [Tr. 2898-2899].

132. Dr. Rios observed first hand Dr. Chein's new patient protocol. [Tr. 2721, 2832-2835]. First, patients are given a "fairly thorough evaluation" by taking some scans or studies that "measure how they would function for their age level." [Tr. 2721-2722]. Then the patients would undergo various tests to measure "their basic chemistries to their various

hormone levels." [Tr. 2722]. Dr. Chein would then review all of these results and meet with the patient. When Dr. Rios is there, he would meet with the patient as well. After Dr. Chein examines the patient, the three of them would discuss the proposed treatment and recommendations. [Tr. 2722]. This intake examination takes a minimum of three to four hours. [Tr. 2722]. Dr. Rios credibly testified that he had never observed a new patient being prescribed hormones without going through this intake process. [Tr. 2722, 2725-2726]. In medical terms, Dr. Rios explained the procedures used as follows:

> the procedure involves a lengthy evaluation, baseline studies in their physiologic function, laboratory studies involving various hormones, a physical examination, vital signs. Then a discussion, meeting with the patient, and education, – after they've done that, then an education on administration of hormones and how this would be done. And any questions they have at that time are answered.

[Tr. 2723-2724].

133. Dr. Rios also treats patients that reside outside of the United States. [Tr. 2893]. He is the primary care physician for such patients. His patients also have doctors in the overseas locations. Primarily, his patients are American citizens who live in Mexico. Commonly, they will have tests conducted in Mexico, and they will bring the test results and other related correspondence with them to their appointments with

Dr. Rios. [Tr. 2894]. Dr. Rios will also review the treatment his patients receive in Mexico, review the medications prescribed, and determine if he agrees with the course of treatment for his patients. If he does not agree, he will make a recommendation to his patient concerning alternative treatments. [Tr. 2894]. Dr. Rios will also engage in telephonic consultations with these overseas patients. However, prior to prescribing medications to his patients, he would need adequate information to make a medical assessment. He credibly stated that "the more (information) you have, the better your decision in terms of how you treat that patient." [Tr. 2895-2896].

134. Dr. Rios was asked to comment upon Dr. Zipser's conclusions in his report, addressing the care given to six patients. At the time of the hearing, these patients were not Dr. Rios' patients, however, and he also had not examined any of them. [Tr. 2864, 2892]. Overall, Dr. Rios credibly stated that he believed all of their charts recorded lab results and that there had been a good faith evaluation of the patients' blood. [Tr. 2910]. He then testified about individual patients based on their medical records.

(a) Patient TY

135. At the hearing, Dr. Zipser reviewed TY's patient chart and his own report comments regarding TY's care. [Tr. 2421; Govt. Exh. 95, Govt. Exh. 112 at 5-6]. TY's chart indicates that a patient history was collected at PSLEI in Seoul, Korea, ("medical clinic")

on July 13, 2000. [Tr. 2422; Govt. Exh. 95 at 33]. The medical record also indicated that the Respondent met this patient at the medical clinic in Seoul, Korea, in July and September of 2000. [Tr. 2560-2561; Govt. Exh. 95 at 24, 26, 29]. In a letter dated August 8, 2000, sent to this patient and addressed to the medical clinic, the Respondent wrote: "It was nice meeting you in Seoul, Korea on July 13, 2000. After I returned, I received your first set of blood tests and there are abnormalities as stated above." [Govt. Exh. 95 at 26]. After describing the treatment that he advised the patient to follow, and after informing the patient that the hormones, including the controlled substances, would be sent from PSLEI in California to the patient in Korea, the Respondent adds: "After thirty to forty-five days from the start of the program, please repeat the blood test so that I may adjust the dosages if necessary." [Govt. Exh. 95 at 26, 29]. From this correspondence, I find that the record supports the inference that the Respondent was at the medical clinic in Korea when this patient's initial examination was conducted. [*See also* Tr. 2563-2564].

136. As part of the history, the patient indicated that she had a history of breast cancer in 1992. Also, at the hearing, Dr. Zipser credibly testified that TY's blood pressure was "extremely high," as recorded in this history. [Tr. 2423; Govt. Exh. 95 at 33].

137. TY's chart also contained a letter from the Respondent dated November 21, 2001. In this letter, the Respondent addresses three problems raised by the patient. At the hearing, Dr. Zipser agreed with

the Respondent's initial advice, that this patient should get a cardiac consultation. [Tr. 2426-2427; Govt. Exh. 95 at 11]. However, Dr. Zipser credibly testified that this patient's chart does not demonstrate that she followed the Respondent's advice, or that the Respondent continued to monitor her blood pressure. [Tr. 2427]. Dr. Zipser found this worrisome, for the Respondent continued to prescribe medications to this patient that can affect blood pressure. [Tr. 2427-2428]. To be within the standard of care, Dr. Zipser opined that the Respondent would need to continue to monitor this patient's blood pressure and "cardiac rhythm and rate" while he continued to prescribe these medications. [Tr. 2428]. Consistent with his testimony, Dr. Zipser wrote in his report that this failure to continue to monitor these conditions "indicates an extreme departure from the standard of care. [Govt. Exh. 112 at 6; *see also* Tr. 2430-2435].

138. Also, Dr. Zipser credibly noted that, after reviewing all of the medications the Respondent prescribed to TY, he would expect follow-up examinations to occur "on an ongoing basis, perhaps every two weeks, perhaps a month or even two months as the patient becomes more stable." [Tr. 2436]. Then, once the patient is stabilized on these medications, Dr. Zipser opined that the visits to the Respondent could be expanded to occur only once every several months. [Tr. 2436]. Such recurring visit schedules would be the standard of care, for the standard of care requires a physician to perform a good faith examination before the physician prescribes a medication. The

prescribing physician is the responsible physician. [Tr. 2436, 2522-2524].

139. Dr. Zipser also concluded that continuing to prescribe estrogen to a patient with a history of breast cancer indicates an extreme departure from the standard of care. [Govt. Exhs. 95, 112 at 4-5; Tr. 2744, 2845]. At the hearing, Dr. Zipser credibly explained, stating that many "breast cancers are responsive to estrogen. To administer estrogen to a patient who has a known current or previous breast cancer is just extremely severe departure from the standard of care. This would have the potential to exacerbate the breast cancer. And it is contraindicated to give estrogens to such a patient." [Tr. 2428]. Yet, upon cross-examination, Dr. Zipser also noted that controversy exists within the medical profession "regarding the safety of hormone replacement therapy after a diagnosis of breast cancer." [Tr. 2566].

140. Dr. Rios was asked to comment regarding TY's care, especially about the fact that she had been administered hormone replace [sic] therapy, to include estrogen, after treatment for breast cancer. Dr. Rios assumed that he and Dr. Zipser had reviewed the same patient chart for TY, and Dr. Rios disagreed with Dr. Zipser's opinion concerning the quality of the care received by TY. [Resp. Exh. 1084; Tr. 2758-2781, 2848]. In reaching his conclusion, Dr. Rios cited to a study conducted by Dr. DiSaia, with a basic conclusion "that it is not fair to deny prior breast cancer patients the benefit of hormone replacement therapy. It should be based on individual patients, and it

should be closely monitored." [Tr. 2745-2746]. Dr. Rios continued, noting that "it's not unreasonable to use estrogen in patients that have had previous breast cancer for them to receive the benefits. And a lot of the benefits . . . involve what anti-aging is all about." [Tr. 2745-2746]. Dr. Rios also supported his opinion by referring to a journal article, "Breast Cancer Survival and Hormone Replacement Therapy," which appeared in the *American Journal of Clinical Oncology*. [Resp. Exh. 1083; Tr. 2746-2755]. Dr. Rios referred to numerous other studies on this topic that complied with his view. [Tr. 2756-2758]. Dr. Rios also credibly testified that treatment of women with breast cancer using estrogen replacement therapy remained controversial within the medical profession. [Tr. 2861].

(b) Patient HY

141. Dr. Zipser succinctly stated what information he was evaluating to determine the Respondent's deviation from the standard of care in his treatment of patient HY. Specifically, Dr. Zipser credibly testified as follows:

> What I am applying in the evaluation of medications that were prescribed from Palm Springs, California, is whether there was a physical examination done on the chart that is consistent with a good-faith history and physical. If the records contained a history and physical done by another physician, as I said earlier, in another country and that is on the record, and the physician in Palm

> Springs says, 'History and physical reviewed and agreed,' that would imply that he was appropriately examined and that there was an appropriate indication or an appropriate basis for then going on to the next step of concluding a diagnosis and concluding a treatment.
>
> I am not judging what a Japanese physician does in Japan. I am judging what is on the medical records for the physician to prescribe the medicine in Palm Springs.

[Tr. 2589-2590].

142. Patient HY complained of increased heart rate and palpitations on exertion. [Tr. 2454; Govt. Exh. 97 at 6]. Dr. Zipser credibly testified that such complaints are cardiac symptoms, and the patient's taking of thyroid hormone may also affect the cardiac system. [Tr. 2454]. However, although the Respondent conducted a blood test, no physical examination is documented on the date the patient reported these symptoms. [Tr. 2454-2455; Govt. Exh. 97 at 35].

143. Dr. Zipser concluded that the Respondent's treatment of HY was an extreme departure from the standard of care In his expert report, Dr. Zipser determined that the Respondent's care failed to meet standards because (1) no physical examination had been documented in the patient's record prior to the Respondent's prescribing of medications, and (2) the lack of follow-up examinations during the Respondent's ongoing treatment of this patient. [Tr. 2457-2461; Govt. Exh. 112 at 6].

144. However, the patient's medical records reflect that the Respondent saw HY on May 24, 2000, in a medical clinic in Japan. [Tr. 2569; Govt. Exh. 97 at 35]. The Progress Note, however, indicated that the Respondent needed to obtain additional blood test results from HY before adjusting hormone levels in response to HY's complaints. Yet, the chart does not indicate that the Respondent conducted a physical examination on this date. [Tr. 2569-2575; Govt. Exh. 97 at 35].

145. Dr. Rios disagreed with Dr. Zipser's conclusion, credibly testifying as follows:

> The patient is being seen by a primary (care physician) in a location where Dr. Chein has visited. There is a primary physician that is attending this patient in the Japan clinic. And there is also ongoing records indicating ongoing care and studies being done on this patient.

[Tr. 2782-2783; *see also* Tr. 2865-2866; Resp. Exh. 1085 at 67].

(c) Patient RZ

146. RZ's chart contains a completed patient history. [Govt. Exh. 101 at 134-145]. Further, the chart contains an "Agreement for Medical Services", wherein the patient is informed that PSLEI and its physicians "are only responsible for the evaluation and prescription of hormone replacement therapy." [Govt. Exh. 101 at 146]. Further, RZ certified: "I am

under the care of another physician(s) for all other medical conditions. I will consult my other physician(s) for any other medical services I may require." [Govt. Exh. 101 at 147]. Lastly, the chart clearly explains to RZ that Medicare would most likely not pay for services provided at PSLEI. [Govt. Exh. 101 at 150].

147. RZ's patient chart shows that Drs. Chein and Garber ordered periodic laboratory tests with the results being posted in the chart. [Govt. 101 at 85-101, 115-123, 124-132]. The Respondent prescribed testosterone and phentermine to RZ. [Govt. Exh. 101 at 73]. Also, the chart contains entries indicating that the Respondent, Dr. Garber, and Dr. Vogt all took part in treating RZ. [*See, e.g.*, Govt. Exh. 101 at 36, 37, 45, 47, 73, and 85]. At the hearing, Dr. Zipser credibly noted that it was difficult to separate one physician's care from another's in the chart. [Tr. 2499-2500].

148. The two expert witnesses disagreed on the standard of care afforded patient RZ. [Govt. Exhs. 112 at 7, 101; Resp. Exh. 1086; Tr. 2783-2789].

149. At the hearing, Dr. Zipser noted that the Respondent had approved, in RZ's medical chart, the patient's taking phentermine for anxiety. [Tr. 2409; Govt. Exh. 101 at 47]. Dr. Zipser then credibly testified that it "would be inappropriate to administer phentermine for the purpose of treating anxiety. . . . If anything, this amphetamine-like drug would increase anxiety." [Tr. 2409-2410].

150. Next, Dr. Zipser credibly testified concerning what follow-up care was needed for a patient prescribed phentermine. Specifically, Dr. Zipser explained:

> [T]he standard of care is to perform follow-up physical examinations and history. This is done because this type of medication can have cardiac side effects, cardiac arrhythmias, can even cause death, can affect anxiety, increasing anxiety. Therefore, the standard is that patients have to be followed on a regular basis.
>
> That follow-up would include getting a history, examining the cardiac system, often performing EKG examinations or other cardiac tests. The frequency of examination is generally in the range of every few weeks. Perhaps when a patient is stable, one might do it less often than every two or three or four weeks. They may go two months perhaps, but certainly a reasonably close follow-up.

[Tr. 2413-2414].

151. Dr. Zipser acknowledged that RZ's chart contained communications indicating that RZ had treating physicians in Spain. [Tr. 2489-2490]. Further, RZ certified that she would seek treatment from her attending physicians. [Tr. 2492; Govt. Exh. 101 at 147].

152. Dr. Zipser also knew that RZ's patient chart had lab tests results. [Tr. 2492; Govt. Exh. 101 at 51-52, 76-84].

153. Although RZ's chart contains progress notes, Dr. Zipser indicated that such notes did not equate with adequate follow-up care. Specifically, Dr. Zipser credibly testified that the progress notes "indicate communication. There is not the sort of follow-up of a history and physical examination that is the standard." [Tr. 2509].

154. RZ complained of carpal tunnel syndrome. [Govt. Exh. 101 at 59]. Regarding this complaint, Dr. Zipser credibly stated: "One of the medications, growth hormone, can cause carpal tunnel syndrome as a side effect and can exacerbate it if it is already preexisting." [Tr. 2417].

155. As for side effects experienced by RZ, Dr. Zipser also notes in his report:

> In several letters the patient reported possible complications of her hormone therapy with symptoms of carpal tunnel syndrome suspected to be due to growth hormone administration and possibly hormone-induced hair loss (alpecia areata), mood swings, palpitations, acne, and weight gain.

[Govt. Exh. 112 at 8]. From this observation, Dr. Zipser concluded that the "continued administration of these medications after multiple communications from the patient listing several side effects represents an extreme departure from the standard of care." [Govt. Exh. 112 at 8].

156. After reviewing this patient's medical chart, Dr. Zipser wrote the following conclusion:

> The failure to perform follow-up physical examination(s) following prescription of multiple medications that have potential severe side effects, including thyroid hormone, growth hormone, testosterone and phentermine represents an extreme departure from the standard of care. The failure to perform adequate cardiac evaluation including EKG prior to therapy with phentermine represents a departure from the standard of care.

[Govt. Exh. 112 at 8; *see also* Tr. 2417-2421].

157. However, Dr. Rios also credibly testified regarding Dr. Chein's treatment of RZ. [Tr. 2783-2789]. He concluded that the Respondent's treatment was "not an extreme departure from the standard of care based on the community in which I practice." [Tr. 2784]. To support his conclusion, Dr. Rios notes that "there is evidence in the record of the patient being seen by physicians in Spain where she resides. When she came to (PSLEI), she came with extensive laboratory work done in Spain." [*Id.*]. Dr. Rios also disagreed with Dr. Zipser's conclusion that Dr. Chein's failure to conduct an electrocardiogram on RZ prior to prescribing phentermine was a departure from the standard of care. [Tr. 2785-2786]. Further, in his experience in this field regarding the prescribing of phentermine, none of his patients have ever

experienced the cardiac complications that Dr. Zipser's references in his report. [Tr. 2786-2787].

158. Dr. Rios also credibly testified that:

> There is evidence in the record that this patient both communicated concerns about side effects, and she sought opinions from other physicians in Spain regarding the side effects.

[Tr. 2787, 2889-2891]. Further, some of her treatments were changed, and some of her side effects resolved. Dr. Rios also noted that record entries indicated ongoing treatment by RZ's primary physicians in Spain. [Tr. 2788]. Dr. Rios also pointed out that there had been discussions between RZ and the physicians at the Respondent's clinic regarding side effects and test results, and that RZ's medication was adjusted. [Tr. 2789].

(d) Patient ML

159. This patient's file demonstrates a patient history was taken on November 22, 1999. On this form, ML's blood pressure is recorded as 150 over 90. [Tr. 2463; Govt. Exh. 104 at 62]. At the hearing, Dr. Zipser credibly testified that this blood pressure reading demonstrated a mildly elevated blood pressure. [Tr. 2464]. The medical chart also indicates that the patient had an EKG in 1999 with "normal" results. [Tr. 2624; Govt. Exh. 104 at 76].

160. ML's patient file also contains a physical examination form dated January 17, 2000. On that form ML's blood pressure is recorded as 136 over 92. Dr. Zipser again credibly testified that this number indicates a slightly elevated blood pressure. [Tr. 2461-2462, 2465; Govt. Exh. 104 at 23].

161. Next, the patient file contains a physical examination form dated August 24, 2000, with a blood pressure recorded as 129 over 91. Dr. Zipser credibly testified that this blood pressure was mildly elevated. He concluded: "This is consistent with the previous two blood pressures, indicating a mild degree of diastolic hypertension. That is, the lower number is increased and would again support that this patient has a chronic hypertensive disorder." [Tr. 2466; Govt. Exh. 104 at 21].

162. Given this pattern of blood pressure readings, Dr. Zipser credibly testified that he was concerned about ML receiving thyroid hormones and phentermine. He stated: "Thyroid hormone, when given in increased amounts, can affect cardiac function, including cardiac arrhythmias. Phentermine has a potential for very serious effects on the heart, including cardiac arrhythmias, potentially sudden death, as well as both drugs' potential for exacerbation of hypertension." [Tr. 2467, 2469-2470].

163. ML's chart also contains a "Progress Note" dated August 14, 2001. On this foam, ML's blood pressure is recorded as 102 over 67, a normal reading. [Tr. 2467; Govt. Exh. 104 at 20; *see also* Tr. 2621].

164. Given the patient's medical pattern, Dr. Zipser credibly testified that follow-up examinations were needed, especially in light of the medications being prescribed. Such a follow-up examination should have been conducted within a few weeks of the initial examination and prescription of the medications. The exam should include, at a minimum, a taking of a history, and a brief physical examination of the "involved organ systems, primarily, compared to the heart and lung exam." [Tr. 2468]. The examination should also include "measurement of blood pressure, pulse, examination of the heart and lungs, and a history related to the cardiovascular system, such as palpitations, trouble breathing, [and] chest pain." [Tr. 2469]. Also, initially, there should have been an EKG or other cardiac evaluation. [Tr. 2469, 2621]. However, this medical record did not include indications that such examinations were performed. [Tr. 2469].

165. Dr. Zipser and Dr. Rios disagree regarding the treatment of patient ML and the standard of care. Specifically, Dr. Zipser wrote: "The prescribing of phentermine with potential severe cardio-vascular side effects, in a patient with hypertension and with failure to obtain an EKG[5] and to perform adequate

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[5] Dr. Zipser credibly testified that an initial EKG report was in this patient's chart. Thus, this aspect of his criticism of the Respondent's care in his written report was revised during his testimony at the hearing. [Tr. 2624-2625; Govt. Exh. 112].

follow-up examinations represents an extreme departure from the standard of care." [Govt. Exh. 112 at 9].

166. Dr. Rios disagreed, testifying that the Respondent's treatment of ML was not an extreme departure from the standard of care. [Resp. Exh. 1087; Tr. 2790]. Specifically, Dr. Rios found that the patient's blood pressure was declining over time and was "normal approximately a year or eight months after this patient had been on the regimen that Dr. Chein had recommended for anti-aging." [Tr. 2791, 2872]. Dr. Rios thought the patient's results "included probably some of the benefits of perhaps weight loss or other things that are seen with this type of regimen." [*Id.*; *see also* Tr. 2872].

(e) Patient KH

167. Again, Dr. Zipser and Dr. Rios disagreed concerning the treatment and standard of care for patient KH. [Govt. Exhs. 112 at 9, 105; Resp. Exh. 1088; Tr. 2791-2794]. At the hearing, Dr. Zipser reviewed this patient's medical record, noting that the patient's blood pressure was recorded in the chart, but that the remainder of the initial examination documentation was blank. [Tr. 2445-2446; Govt. Exh. 105 at 76]. However, the chart revealed that this patient was prescribed albuterol, a drug used to treat pulmonary problems, "testosterone and phentermine, all of which have serious potential effects on multiple organ systems. A physical examination is absolutely

required prior to the administration of these medications." [Tr. 2447].

168. Dr. Zipser also noted that the record contained no indication of follow-up examinations. [Tr. 2447]. Dr. Zipser credibly testified that such examinations would be needed, given the medications the patient was prescribed. [Tr. 2447-2448].

169. Dr. Zipser was also concerned that this patient was prescribed testosterone without follow-up care, as noted in the records. Dr. Zipser credibly testified:

> Testosterone is a regulated substance and has potential serious side effects, as well as non-serious side effects. . . . thus, it would be important that the patient have follow-up as well as the initial history and physical examination. To prescribe this medication in the absence of good-faith history and physical examination is an extreme deviation from the standard of care.

[Tr. 2451-2452].

170. Dr. Zipser concluded:

> The prescribing of phentermine with potential severe cardio-vascular side effects, in a patient with hypertension and with failure to obtain an EKG and to perform adequate follow-up examinations represents an extreme departure from the standard of care. The failure to perform an initial examination and follow-up examinations during treatment

> with multiple medications that have potential serious side effects represents an extreme departure from the standard of care.

[Govt. Exh. 112 at 9; *see also* Tr. 2448-2450].

171. However, Dr. Rios disagreed, noting entries in the medical record consistent with on-going care by the patient's primary physician, as well as indications that the Respondent saw this patient when he traveled to Japan. Specifically, in a letter dated October 14, 1999, the Respondent reviewed blood test results, advised on dosage changes for the hormones prescribed, and advised the patient to have specific medical tests taken. [Tr. 2646-2662, 2793-2794, 2872-2873; Govt. Exh. 105 at 29-30, 48; Resp. Exh. 1088 at 1-7].

172. However, after reviewing this letter, Dr. Zipser still found that the Respondent's medical practices were deviating from the standard of care. Dr. Zipser credibly explained:

> The judgment of the standard of care reflects what is available in the medical records . . . And the physician in Palm Springs is writing orders or giving orders and actually sending the medication to this patient, yet the records do not show follow-up examination. And that is a departure of standard of care.

[Tr. 2650]. He further testified that he is making this judgment based upon what is in the Respondent's medical records, and "if it's not in the records, then we assume it did not occur." [Tr. 2651].

173. Also, like in the other cases, Dr. Rios disagreed with Dr. Zipser's assertion that an EKG is needed prior to prescribing phentermine to this, or any other, patient. [Tr. 2793, 2868-2869]. Yet Dr. Rios also acknowledged that the patient's chart that he had reviewed lacked a completed physical examination form. [Tr. 2858-2859].

(f) Patient HM

174. Dr. Zipser credibly noted that patient HM's chart contained no initial physical examination or any follow-up examinations. [Tr. 2471; Govt. Exh. 110]. Yet the chart reflected that HM received phentermine and testosterone.

175. In light of these prescriptions, Dr. Zipser credibly testified that he was concerned that HM needed ongoing screening for cardiac system problems due to the phentermine prescriptions, and behavior and prostate tumor screening due to the testosterone prescriptions. [Tr. 2471-2472]. Further, the combination of the drugs being prescribed to HM "increases the risks" for this patient. [Tr. 2475].

176. HM also received prescriptions for growth hormones. Yet, HM had a diagnosis of borderline diabetes, which may be affected by growth hormones. [Tr. 2472]. Specifically, Dr. Zipser credibly testified that "[g]rowth hormone[s] alter the metabolism . . . [for] it can increase blood sugar. And it would require post monitoring of the sugar." [Tr. 2472].

177. Dr. Zipser credibly stated that an initial physical examination and follow-up examinations would be needed for HM, because the medications prescribed to HM had potential side effects that "could exacerbate underlying diseases." [Tr. 2473]. He stated: "So it's very important to find out what other disorders the patient has, whether they will tolerate the medication, whether they're appropriate, whether they're indicated. One cannot safely prescribe medication without going through the process of a good-faith history and physical examination." [Tr. 2473].

178. As for HM's follow-up examinations, Dr. Zipser found that they would be even more vital here, for HM needed to be examined "for complications of the diabetes which could have been exacerbated by the medication, such as changes in vision, changes in blood pressure, [and] cardiac function." [Tr. 2474-2475].

179. Again, Dr. Zipser and Dr. Rios disagreed concerning the Respondent's treatment and the standard of care evaluation for HM. [Tr. 2794-2798; Govt. Exh. 112 at 11; Resp. Exh. 1089]. Dr. Zipser wrote in his report that the Respondent's treatment of this patient represented an extreme departure from the standard of care because the Respondent had failed to perform an initial physical examination prior to prescribing medications, to include thyroid and growth hormone medicines. Further, per Dr. Zipser, the Respondent had failed to perform follow-up examinations during his treatment of this patient. [Govt. Exh. 112 at 11].

180. Yet Dr. Rios notes that, based on the community where he practices anti-aging medicine, "the primary physician would be involved in doing the initial evaluation and the management of the primary problems." [Tr. 2794-2795].

C. Facts Regarding Export Registration

181. Prior to exporting a controlled substance, an entity needs to obtain a registration with the DEA. [Govt. Exh. 38, citing to 21 U.S.C. 957]. Applications for such a registration are evaluated under the standards established in 21 U.S.C. section 958. An applicant violates the Controlled Substances Act if (1) he exports a controlled substance prior to obtaining this DEA registration and (2) if he fails to follow the other regulatory requirements for exporting controlled substances. [Govt. Exh. 38; 21 U.S.C. 957].

182. On or about April 27, 2001, the Respondent filed an application for a DEA exporter's registration. [Govt. Exh. 39; Tr. 585-587].

183. DI Sean Mahoney credibly testified at the hearing and provided a written declaration. [Tr. 2230-2301; Govt. Exh. 38]. DI Mahoney has worked for the DEA since October of 1970, and he is currently serving as the Chief of the International Drug Unit, Office of Diversion and Control, at DEA Headquarters. [Tr. 2230].

184. DI Mahoney credibly explained that it would be a violation if an entity knowingly or intentionally imported or exported a controlled substance without a valid DEA registration, or "without going through the process of a registration and submission of the necessary paperwork." [Tr. 2276; Govt. Exh. 38].

185. To export a Schedule III or Schedule IV substance, once a DEA registration is received, the registrant must file a declaration. For example, prior to exporting an anabolic steroid, a Schedule III substance, or Phentermine, a Schedule IV substance, the Respondent, after receiving his DEA registration as an exporter, would need to file the required declaration. [Govt. Exh. 38; 21 U.S.C. 953(e)]. Such declarations need to be filed prior to the export actually taking place. [Govt. Exh. 38]. Again, it is a violation of the Controlled Substances Act to export such substances without filing the requisite declarations. [Govt. Exh. 38; 21 U.S.C. 953, 960].

186. Neither the Respondent nor the Palm Springs Life Extension Institute is registered with the DEA to engage in export activities. [Govt. Exh. 38]. Further, neither the Respondent nor the Palm Springs Life Extension Institute filed any export declarations with the DEA for the controlled substances shipped out of the United States.

187. DI Mahoney credibly testified that the DEA is more likely to seek an administrative proceeding against a registrant who knowingly violates DEA

regulations, than against a registrant who makes a mistake, is instructed by the DEA regarding that mistake, and corrects the registrant's business practices. [Tr 226-2278].

188. Also, DI Mahoney credibly stated that, no matter what amount of controlled substances shipped from the United States to a recipient in a country overseas, the competent authority in the receiving country "must approve of this amount [of controlled substances] coming into their country." [Tr. 2289-2290].

189. DI Wayne Michaels credibly testified and provided a declaration for this proceeding. [Tr. 2320-2362]; Govt. Exh. 38(c)]. DI Michaels has worked for the DEA since 1985, and he is currently assigned as a staff coordinator in the International Drug Unit at DEA Headquarters. [Tr. 2320-2321].

190. DI Michaels explained the process to be followed by an entity wishing to become registered as an exporter and seeking to export controlled substances from the United States. Specifically, the purpose of DEA's evaluation of the import and export requests is to ensure that "the United States adheres to its international treaty obligations."[6] [Govt. Exh.

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[6] DI Michaels was questioned extensively about his participation in a conference call wherein he explained the above procedures to Dr. Darryl Garber [Tr. 2323-2350; [Govt. Exh. 38(c) at 3-4]. I find this information of limited relevance to this proceeding involving Dr. Chein, and therefore I make no further

(Continued on following page)

38(c) at 1]. Further, our "treaty obligations are designed to assure that both the country of origin and country of destination have the opportunity to evaluate a transaction involving a controlled substance prior to the transaction taking place." [Govt. Exh. 38(c) at 2]. DI Michaels credibly explained that "a physician within the United States who desires to send anabolic steroids (Schedule III) and/or phentermine (Schedule IV) to patients who are located outside of the United States, must obtain a separate DEA export registration." [Govt Exh. 38(c) at 2]. Further, such distribution of anabolic steroids and phentermine constitute an "export" within the meaning of the Controlled Substances Act. [Govt. Exh. 38(c) at 2]. A physician is not allowed to use his "physician registration" as authority to export controlled substances to patients residing outside of the United States. [Govt. Exh. 38(c) at 2; *see also* 21 C.F.R. § 1301.13(e)(iii), (vii), and (viii)]. The physician would also need to file a declaration with the DEA "along with documentary proof that the . . . export does not violate the laws of the host country." [Govt. Exh. 38(c) at 3; *see also* 21 U.S.C. 952 and 953 and 21 C.F.R. §§ 1312.27 and 1312.28]: The declaration must confirm that "the recipient of the controlled substances shipment in the destination country is authorized to handle and/or receive the controlled substance, and that the substance is being shipped to

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findings regarding this conference call based on DI Michael's testimony.

satisfy medical, scientific or other legitimate purposes." [Govt. Exh. 38(c) at 3; *see also* 21 C.F.R. §1312.27(b)(4)(i)]. Any failure to comply with this process "deprives the competent authority in the destination country from determining whether the receipt of the shipment is consistent with the destination country's domestic laws and international treaty obligations." [Govt. Exh. 38(c) at 3]. For example, the record contains credible documents which indicate that Taiwan and Japan prohibit the importation of phentermine. [Govt. Exh. 38(c), attachments D and E].

191. The dispensing documents retrieved from the Respondent's clinic on February 5, 2001, contained references to patients residing outside of the United States who were dispensed controlled substances. [Tr. 292-316; Govt. Exh. 10, 11, 12, 15, 16]. DI DeSantis credibly testified that, between July 1, 2000, to February 5, 2001, there were 317 instances where controlled substances were dispensed to patients outside of the United States. [Tr. 318; Govt. Exh. 46 at 7; *see also* Govt. Exh. 52 and Tr. 699; Govt. Exh. 56 and Tr. 705-707; Govt. Exh. 70 and Tr. 719; Govt. Exh. 72 and Tr. 720; Govt. Exh. 76 and Tr. 743-746; Govt. Exh. 107 at 20 and Tr. 818-824; Govt. Exh. 121 and Tr. 749-750;].

192. Some of the shipments sent from PSLEI were mislabeled to avoid disclosing that the package contained controlled substances. For example, one message sent to a patient of PSLEI stated that the controlled substance "is being shipped via postal

express, and Maryanne will be shipping it and wrapping it as a skin cream and as a gift for Customs purposes and he's stating don't be misled, it will be, in fact, testosterone." [Govt. Exh. 107 at 21; Tr. 823-825, 1592-1595].

193. The Respondent told DI DeSantis that he was not sending controlled substances directly to his overseas patients. Rather, he was sending the controlled substances overseas to doctors treating his patients there. [Tr. 1205]. DI DeSantis informed the Respondent that he would need to submit an application to the DEA for an exporter's registration. She also sent the Respondent a copy of 21 United States Code section 953(a). [Tr. 1002].

194. Although DI DeSantis asked the Respondent three times to stop exporting controlled substances until properly registered with the DEA, the Respondent did not comply with her requests. [Tr. 1209-1210, 1214-1215, 1246]. The Respondent disagreed that he was improperly exporting controlled substances. Rather, he believed he was dispensing controlled substances to his patients. [Tr. 1210]. The Respondent told DI DeSantis that he would not stop sending controlled substances overseas unless the DEA ordered him in writing to stop his practices. [Tr. 1222].

195. On March 9, 2001, DI DeSantis informed Dr. Garber, a physician at PSLEI, that it was illegal to ship controlled substances overseas without an

exporter's registration from the DEA. [Tr. 508]. DI DeSantis provided Dr. Garber with a copy of 21 United States Code section 953, "Exportation of Controlled Substances," and 21 United States Code section 960, "Prohibited Acts." [Tr. 509-510; Govt. Exh. 19].

196. Dr. Garber's reply to this information was a statement that the clinic had patient files for each of the patients to whom he shipped controlled substances. [Tr. 513].

197. In April of 2001, the Respondent submitted an exporter's registration application. [Tr. 1247; Govt. Exh. 48]. This application was not processed, as indicated by a lack of a control number on the application. [Tr. 2092-2094; Govt. Exh. 48 at 3]. However, a credit card payment was processed. [Tr. 2094, 2149; Govt. Exh. 48 at 5]. Subsequently, the Respondent's credit card received a credit for the fee charged for this registration, and the DEA did not process this application further. [Tr. 1225-1226, 2094-2104; Govt. Exh. 48 at 5-6].[7]

198. On or about October 24, 2001, the Respondent wrote to DI DeSantis, asking about the status of

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[7] The record contains extensive testimony concerning the processing, or lack thereof, of this application. [Tr. 2180-2216]. However, I find that no additional findings of fact need to be made relevant to this proceeding.

his initial export registration application. [Govt. Exh. 39]. Attached to the letter was a copy of the application, dated April 27, 2001. When DI DeSantis received the letter and attachment, she searched the DEA's registration database to determine the status of this application. However, she determined that "there was no entry for Doctor Chein as an exporter." [Tr. 661]. A DEA representative wrote back to the Respondent, informing him that the DEA had "no record of such an application in [his] name." [Govt. Exh. 40; Tr. 662-666].

199. By letter dated November 8, 2001, the Respondent again submitted an export registration application, sending in a copy of the document dated April 27, 2001. [Govt. Exh. 34].

200. In December of 2001, the Respondent again filed an application for registration as an exporter. [Govt. Exh. 48 at 7-8].

201. An Order to Show Cause dated May 24, 2002, was issued by DEA in response to the Respondent's application for registration as an exporter of controlled substances. [Govt. Exh. 49].

D. Facts Regarding Import Issue

202. The DEA does not register overseas pharmacies or distributors. [Tr. 573-574].

203. The Respondent provided the DEA with an invoice indicating that PSLEI purchased controlled substances from a Mexican company, which was not a

DEA registrant. [Tr. 574; Govt. Exh. 22]. Specifically, the invoice indicated that a controlled substance was shipped to the Respondent's clinic by Farmacia. The invoice noted that Farmacia is located in Mexico. [Govt. Exh. 22]. The invoice contained no DEA registration numbers. [Tr. 574-575]. At the date of the shipment, PSLEI was owned by the Respondent. [Tr. 575]. The Respondent is not registered to import controlled substances. [Tr. 970]. However, DI DeSantis had no direct evidence demonstrating that the Respondent received a controlled substance shipped from Mexico to PSLEI. This invoice was the only evidence in the record related to Farmacia. [Tr. 980-981].

204. DEA was also investigating a firm named Farmacia, and its owner, Dr. Romero. [Tr. 160]. Dr. Romero was kidnapped in mid-October, 1993, and subsequently murdered. [Tr. 160-61]. However, DI Brasich credibly testified that he knew that Dr. Romero was receiving funds in San Diego County, and he felt it was logical that Dr. Romero, "like many other Tijuana physicians and farmacias, were probably smuggling the drugs into San Diego and shipping them." [Tr. 161-62, 167]. Yet Dr. Romero also required individuals to go to Mexico and to bring the drugs into the U.S. themselves. [Tr. 162].

205. Dr. Romero lived in Chula Vista, California, and owned a few pharmacies in Tijuana. [Tr. 166]. Dr. Romero was not registered with the DEA. [Tr. 167]. DI Brasich did not have evidence from his investigation that Dr. Romero was storing medicines

and controlled substances at his location in California. [Tr. 173].

206. However, Vanessa Koen, an assistant at PSLEI, credibly testified that she had records, prior to the DEA's seizure of PSLEI records in October 2002, that indicated that shipments of controlled substances were made from Dr. Romero at a location in San Diego, California, to PSLEI. [Tr. 1503-1510].[8]

207. During 2002, DI DeSantis conducted "trash runs" at the location of PSLEI in Palms Springs. [Tr. 686]. During one of these investigations into PSLEI's trash, DI DeSantis recovered approximately 50 empty boxes with Spanish labeling. [Govt. Exh. 58; Tr. 710]. After having the labels translated, DI DeSantis determined that the boxes purported to contain testosterone that was not for human consumption, but rather was for veterinarian use. [Govt. Exh. 58; Tr. 710-713]. From the label, DI DeSantis concluded that the product had been manufactured in Mexico. [Tr. 712].

208. The record contains a sworn declaration of James Smith, Associate Counsel with the Office of Chief Counsel, Food and Drug Administration, ("FDA"), U.S. Department of Health and Human Services. [Govt. Exh. 116]. Mr. Smith credibly writes:

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[8] At the time of the hearing, these records were in the possession of the Government. Despite numerous requests by the Respondent, the Government refused to release the documents pertaining to these shipments.

> For the purposes of this declaration, I am setting forth the violations which would exist pursuant to the FDCA if a practitioner, such as a medical doctor, were importing, repackaging, and/or dispensing to human patients, Testosterona 200^{R}, a steroid that was manufactured at Brovel Laboratories in Mexico City, Mexico, where the labeling, written only in Spanish, indicated that the manufacturer of the product intended that it be used as an intramuscular injectable drug solely in large animals (cattle, horses, sheep and pigs) for treatment of a variety of problems, including sexual impotence, testicular deficiencies, and to speed the healing of fractures.

[Govt. Exh. 116 at 3]. Also, Mr. Smith credibly wrote that it is illegal for an entity to receive, or to offer for pay, any misbranded drug. When testosterone is used as a human drug, it is a prescription medication only. [Govt. Exh. 116 at 3]. "Any prescription drug which, at any time prior to dispensing, fails to bear on the label of the drug, at a minimum, the symbol 'Rx only,' is deemed to be misbranded." [Govt. Exh. 116 at 3-4]. Further, such labeling needs to appear in the English language. [Govt. Exh. 116 at 4]. Lacking this labeling, the contents would be "misbranded." [Govt. Exh. 116 at 5].

209. Although the record reflects that the DEA had no direct evidence that this testosterone labeled for non-human use was dispensed to the Respondent's patients, [Tr. 1556], I find the record supports such an inference. The packages of such labeled testosterone

where found in the Respondent's trash, and they were empty. The Respondent compounds a gel using testosterone. The Respondent does not treat animals. Accordingly, I find the record supports an inference that this non-human use testosterone was compounded into a testosterone gel which was dispensed to the Respondent's human patients.

IV. CONCLUSIONS OF LAW AND DISCUSSION

A. Position of the Parties

1. Government's Position

The Government asserts that the Respondent's DEA Certificate of Registration should be revoked, and his application to export controlled substances should be denied. [Government's Proposed Findings of Fact and Conclusions of Law ("Govt. Brief") at 128-129]. Specifically, the Government notes that the Respondent "has a pattern of multiple and diverse violations" of the Controlled Substances Act, dating back to 1994, "when he commenced to dispense testosterone and human growth hormone to undercover agents for no legitimate medical reason." [Govt. Brief at 126].

Further, the Respondent authorized numerous exports of controlled substances to patients living in foreign countries without obtaining a DEA export registration. The Government found this conduct particularly egregious because the Respondent continued to export controlled substances even after being told by DI DeSantis to cease such conduct until he was granted an export registration. [Govt. Brief at 126]. Also, some of these export packages were labeled in order to conceal their contents and to deceive customs officials in the receiving country. [Govt. Brief at 127].

The Government also asserts that the Respondent illegally imported controlled substances from Mexico without a DEA registration authorizing such importation. The testosterone imported was labeled for animal use only. [Govt. Brief at 127].

Next, the Government asserts that the Respondent had numerous recordkeeping violations, to include the failure to keep a complete biennial inventory and to keep complete dispensing records. Further, the Respondent's records were not readily retrievable, as required by DEA regulations. [Govt. Brief at 127].

The Government also argues that the Respondent dispensed controlled substances without conducting proper medical examinations, even though he was treating patients who were exhibiting symptoms that would require such pre-dispensing examinations. [Govt. Brief at 127].

Lastly, the Government also notes that the Respondent ordered controlled substances unlawfully by using the DEA registration number of other practitioners. Given this pattern of misconduct, the Government argues that the Respondent's DEA registration should be revoked and his export application denied. [Govt. Brief at 128-129].

2. Respondent's Position

The Respondent asserts that it is not in the public interest to revoke his DEA registration. [Respondent's Proposed Findings of Fact and Conclusions of Law ("Respondent's Brief") at 24]. Specifically, he argues that revocation "should only be granted to protect the public from the flow of controlled substances into illegal channels." [Respondent's Brief at 24]. Here, he asserts, there is no evidence that the Respondent engaged in illegal drug trafficking. Therefore, revocation is not warranted. [Respondent's Brief at 24].

The Respondent wrote that his records were readily retrievable and that the IDEA obtained all the requested records. [Respondent's Brief at 25]. He always acted in good faith in his dealings with the DEA personnel. [Respondent's Brief at 25]. Further, the Respondent argues, he was not required to have a DEA export permit to dispense controlled substances to his patients. [Respondent's Brief at 26]. Also, the Respondent did not illegally import controlled substances from Mexico. Rather, all shipments to the Respondent's clinic originated in the United States. [Respondent's Brief at 27].

Lastly, the record contains no evidence of diversion by the Respondent. Specifically, the controlled substances dispensed by the Respondent remained within the lawful distribution chain between the manufacturer, distributor, doctor and patient. [Respondent's Brief at 27]. The Respondent argues that he did not depart from the standard of care in his treatment of patients and in his dispensing of controlled substances. Thus, he does not pose a threat to the public health or safety. [Respondent's Brief at 27].

B. Revocation Issue

Pursuant to 21 U.S.C. Section 824(a)(4), the Deputy Administrator[9] may revoke a DEA Certificate of Registration if she determines that the continuance of such registration would be "inconsistent with the public interest" as determined pursuant to 21 U.S.C. section 823(f). Section 823(f) requires that the following factors be considered:

(1) The recommendation of the appropriate State licensing board or professional disciplinary authority.

(2) The applicant's experience in dispensing, or conducting research with respect to controlled substances.

(3) The applicant's conviction record under Federal or State laws relating to the manufacture, distribution, or dispensing of controlled substances.

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[9] The Deputy Administrator has the authority to make such determinations pursuant to 28 C.F.R. §§ 0.100(b) and 0.104 (2003).

(4) Compliance with applicable State, Federal, or local laws relating to controlled substances.

(5) Such other conduct which may threaten the public health and safety.

These factors may be considered in the disjunctive: the Deputy Administrator may properly rely on any one or a combination of these factors, and may give each factor the weight she deems appropriate, in determining whether a registration should be revoked or an application for registration denied. *See Henry J. Schwarz, Jr., M.D.,* 54 Fed. Reg. 16,422 (DEA 1989). Also, in an action to revoke a registrant's certificate, the DEA has the burden of proving that the requirements for revocation are satisfied. 21 C.F.R. § 1301.44(e). The burden of proof shifts to the Respondent once the Government has made its prima facie case. *Thomas Johnston,* 45 Fed. Reg. 72,311 (DEA 1980).

1. Factor One: Recommendation of the Appropriate State Licensing Board

The California Medical Board has taken disciplinary action against the Respondent's medical license on three occasions. First, in 1995 the Medical Board and the Respondent entered into a settlement after the Respondent was charged with engaging in false advertising and failing to obtain a fictitious-name permit. For these actions, the Medical Board revoked the Respondent's medical license, stayed the revocation, and placed the Respondent on probation for three years, with various terms and conditions. [Finding of Fact ("FOF") 49].

In 2000, the Medical Board again took adverse action against the Respondent's medical license, after finding that the Respondent had prescribed medications without indication, had committed repeated negligent acts, and had failed to maintain adequate and accurate records. The Respondent's medical license was revoked. [FOF 50]. However, the Medical Board's decision was set aside by the California Superior Court, and the case was remanded to the Medical Board. Thereafter, the Respondent and the Medical Board entered into a settlement in February of 2002. The Respondent's medical license was revoked, the revocation was stayed, and the Respondent was placed on probation with specified terms and conditions. [FOF 51, 54].

In August of 2002, the Medical Board again initiated action against the Respondent, alleging he engaged in multiple acts of misconduct, to include engaging in gross negligence in his treatment of a patient, of prescribing without medical indication, and of maintaining inadequate records.[10] [FOF 55].

Although the record contains no recommendation from the Medical Board regarding this matter before the DEA, I conclude that the Respondent's history of misconduct weighs in favor of revoking his DEA Certificate of Registration. Throughout the Medical Board's proceedings, the Respondent has exhibited an unwillingness to practice medicine in a manner consistent with the California Medical Board's rules and regulations. Such an attitude regarding rules and regulations, and such conduct, demonstrates that the Respondent's continued dispensing of controlled substances is not in the public interest.

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[10] This matter was pending when the record was closed in this case.

2. Factors Two and Four: Applicant's Experience in Dispensing Controlled Substances and Compliance with Applicable State, Federal or Local Law

The Respondent has engaged in acts that violated the federal Controlled Substances Act. First, in 1995, the Respondent dispensed anabolic steroids, controlled substances, to undercover agents for nonmedical purposes, to enhance muscle building for competition. [FOF 59-60].

Next, during February of 2000, despite the fact that the Respondent's medical license was revoked, the Respondent told an employee to ship controlled substances to a clinic overseas for a patient. [FOF 52]. This action violated the Controlled Substances Act, since the Respondent was not authorized to practice medicine, he was not authorized to dispense controlled substances to patients. Further, in August of 2000, the Respondent, without a DEA registration entitling him to so act, sent controlled substances from an unregistered location in Utah to Japan. [FOF 53]

The Respondent also violated the federal Controlled Substances Act by dispensing controlled substances to patients who resided overseas, without being registered with the DEA as an exporter of controlled substances. [FOF 71, 86]. He engaged in this activity despite being informed by DI DeSantis of the registration requirement. [FOF 78].

Also of concern, the record supports a finding that the Respondent used testosterone labeled for non-human consumption. [FOF 209]. Such conduct is also a violation of the federal Food, Drug, and Cosmetic Act. [FOF 208].

In total, I find this factor also weighs in favor of revoking the Respondent's DEA Certificate of Registration.

3. Factor Three: Conviction Record

The record contains no evidence of the Respondent's being convicted of crimes involving the handling of controlled substances.

4. Factor Four: Compliance with Applicable State, Federal or Local Law

For the reasons cited above, I find that the Respondent's failure to comply with applicable state, federal, and local law is a factor favoring revocation.

5. Factor Five: Such Other Conduct Which May Threaten the Public Health and Safety (a) General Disregard for the Law

The most significant example of the Respondent's conduct which threatens the public health and safety is his general disregard for the law through his deceptive behavior. For example, when the Respondent provided an anabolic steroid to SA Phillips, he advised SA Phillips to cease using the steroids a couple of days before the competition to avoid detection in a drug test. [FOF 59]. The Respondent engaged in similar conduct when advising and prescribing testosterone gel to SA Garcia. [FOF 60].

The record also demonstrates that packages containing controlled substances were being shipped out of the United States and were deliberately mislabeled to avoid customs. [FOF 192]. However, it is unclear whether such conduct occurred at the direction of the Respondent. Nevertheless, the record contains no evidence indicating that the Respondent, once he knew of such conduct, acted to ensure that such deception no longer occurred.

Also, during a search of the Respondent's home, DI DeSantis seized a Nevada driver's license with the Respondent's picture, but with a different name, "Ben Young." [FOF 88]. On the surface, actions such as obtaining a driver's license in an alternate name appear suspicious. Without further explanation from the Respondent, such suspicious conduct raises unanswered question concerning the Respondent's ethical conduct.

Further, although the DEA told the Respondent of his need for an exporter's registration, the Respondent continued to export controlled substances without obtaining such a registration. [FOF 78, 81]. Such disregard for standards of conduct required of a registrant certainly supports a conclusion that this Respondent should be denied the authority inherent in a DEA Certificate of Registration.

(b) *Dispensing Controlled Substances and the Standard of Care*

The DEA's regulation concerning a registrant's dispensing of a controlled substance in Schedules III, IV, and V, states, in relevant part, that an "individual practitioner may administer or dispense directly a controlled substance listed in Schedule III, IV, or V in the course of his/her professional practice without a prescription. . . . " 21 C.F.R. § 1306.21(b). The record contains voluminous evidence relevant to the dispute of whether or not the Respondent lawfully dispensed testosterone, a Schedule III controlled substance, and phentermine, a Schedule IV controlled substance, in the course of his professional practice. [FOFs 3, 4, 105-112, 116-136].

Here, the Respondent is engaged in a relatively new area of practice, anti-aging medicine. [FOF 17, 33, 40, 41-43]. The Respondent's expert witness defined anti-aging medicine as a form of medicine which tries to deal with preventing the diseases associated with aging. [FOF 119]. The Respondent has been granted patents on his unique use of hormone therapy for anti-aging purposes. [FOF 40-45]. Although relatively new, there does exist an American Academy of Anti-Aging Medicine, which conducts seminars and certifies practitioners in this area of medical practice. [FOF 116-118]. However, the American Board of Medical Specialties does not recognize anti-aging medicine as a medical specialty. [FOF 119]. Further, this area of practice also generates some controversy within the medical profession, for there are some practitioners who feel that "medicine should only intervene when there is a disease process." [FOF 119].

Thus, the record clearly indicates that anti-aging medicine, or total hormone replacement therapy, is a new area of medical expertise. The medical community has yet to either completely embrace this area of expertise, or to reject it.

The Government's expert witness, Dr. Zipser, was certified as an expert in internal medicine and endocrinology. [FOF 96]. He reviewed twenty-one of the Respondent's patient's records.

The Respondent also provided an expert witness, Dr. Rios, a family practice physician who was also certified in anti-aging medicine by the American Academy of Anti-Aging Medicine. [FOF 116, 120]. Dr. Rios had also worked with the Respondent, and was familiar with the Respondent's office practices. [FOF

128]. Dr. Rios examined six patient records which had been reviewed by Dr. Zipser. [FOF 134]. In each instance, Dr. Rios disagreed with Dr. Zipser's conclusions concerning the Respondent's conduct and the standard of care as demonstrated through these records. [FOF 140, 145, 148, 156-157, 165-166, 167, 170-171, 173, 179-180].

Given this uncertainty within the medical community and the disagreement between the two expert witnesses about the standard of care and the treatment of these patients, I conclude that the Government has failed to prove this aspect of its case to a preponderance of the evidence. The DEA has previously held that it "remains the role of the treating physician to make medical treatment decisions consistent with a medical standard of care and the dictates of the Federal and State law." It is not the role of the DEA, when the medical community is still defining the standard of care, to dictate a standard of care. *See William F. Skinner, M.D.,* 60 Fed. Reg. 62,887; *Paul W. Saxton, D.O.,* 64 Fed. Reg. 25,073 (DEA 1999); *Wesley G. Harline, M.D.,* 64 Fed. Reg. 72,678 (DEA 1999).

However, Dr. Zipser also noted inadequate medical practices of the Respondent that were not related to this new area of practice. Specifically, Dr. Zipser wrote that the Respondent administered prescription medications to his patients without first conducting physical examinations or appropriate medical testing, without follow-up visits, and without adequate recordkeeping regarding the patient's care. [FOF 109].

I find these observations credible and convincing, despite any contradictions found in Dr. Rios' testimony. [FOF 127, 129, 132]. Therefore, I conclude that, as for the Respondent's failure to meet general medical practices, the Government has met its burden of proof in demonstrating that such failures create a threat to the Respondent's patients, and to the pool of future patients, the public. [FOF 112, 137-138, 142-144, 153, 156, 164-165, 167-170, 172-173, 174-178; *but see* FOF 146-147, 151-152, 157-168, 171, 180].

(c) *Recordkeeping*

Pursuant to 21 Code of Federal Regulations section 1304.11, a registrant dispensing controlled substances must take an initial inventory (section 1304.11(b)) and an inventory every two years thereafter, referenced as a biennial inventory (section 1304.11(c)). Further, "a separate inventory shall be made for each registered location". 21 C.F.R. §1304.11(a). The content of the inventory of a dispenser must comply with the requirements in 21 Code of Federal Regulations section 1304.11(e)(3). Because he is a registrant who dispenses controlled substances, the Respondent is required to maintain specified records for two years. [FOF 64, 66-68]. Further, these records must be readily retrievable. [FOF 65].

As early as 1996, the DEA issued a search warrant at the Respondent's registered location. Although two controlled substances were seized, no records pertaining to these substances were located. Specifically, no inventory records, purchase records, or distribution records were available. [FOF 56]. In 2000, the Medical Board also found that the Respondent failed to maintain adequate and accurate records. [FOF 50].

Again in February of 2001, the Respondent failed to provide the required records to the DEA. Specifically, the Respondent failed to provide the DEA with a biennial inventory. [FOF 69]. He also did not provide invoices. [FOF 61]. Rather, a staff member informed the DEA that the Respondent's invoices were off-site. [FOF 62]. DI DeSantis informed the Respondent and his colleague that failure to maintain the records at the registered location, and failure to provide required records, were violations of the DEA's regulations. [FOF 63, 78].

Although DI DeSantis returned to the Respondent's clinic approximately one month later, the Respondent still failed to produce complete records. Rather, the Respondent produced incomplete dispensing logs, and failed to provide any invoices for the purchase of testosterone [FOF 70, 71, 72].

The DEA executed an administrative inspection warrant approximately one year later. The Respondent again failed to provide documents recording a biennial inventory, as required. [FOF 83].

In November of 2001, the DEA served the Respondent with the Order to Show Cause and again asked for records. The Respondent provided incomplete invoices lacking DEA registration numbers. [FOF 91].

The Respondent's unwillingness or inability to maintain and produce the required records for a DEA registrant supports a revocation conclusion in this case.

(d) *Failure to Oversee the Clinic.*[11]

Except for the brief revocation period, the Respondent was the owner of PSLEI. During his ownership, the DEA found that controlled substances were being stored improperly, for although controlled substances were being ordered and shipped to at least two doctors at PSLEI, the drugs were being stored in a common storage area at the clinic. [FOF 18]. Given the lack of inventory records, this method of storing controlled substances made it virtually impossible to maintain accountability for the substances.

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[11] A major issue in this case is how much misconduct committed by other DEA registrants associated with PSLEI can be attributed to the Respondent as the owner of the clinic. Here, the DEA has pursued action against Dr. Chein's DEA Certificate of Registration. Since I believe the record contains preponderating evidence for resolving this matter without deciding the issue of Dr. Chein's responsibility for the actions of other practitioners related to PSLEI, I will not add, in my analysis section, an analysis of the facts demonstrating improper handling of controlled substances by Dr. Connie Chein or Dr. Darryl Garber. *See, e.g.*, FOF 74-77. Thus, I conclude that this issue, the extent to which the Respondent is accountable for his colleagues' mishandling of controlled substances, need not be determined to resolve this case.

Also during the Respondent's ownership of PSLEI, controlled substances were being invoiced to PSLEI, but were being shipped to Dr. Garber's home. [FOF 82]. Yet, neither invoice contained a DEA registration number. After February 2001, Dr. Garber's home was no longer his registered location, for his registration had been modified to PSLEI's address. [FOF 76]. However, even after this modification date, controlled substances intended for use at PSLEI were actually shipped to Dr. Garber's residence. [FOF 77, 91]. This handling of controlled substances violated the Controlled Substances Act.

Also, during Dr. C. Chein's ownership of PSLEI, invoices were received which showed that her DEA registration number was being used to order controlled substances, and those drugs were being shipped to PSLEI. [FOF 90]. However, Dr. C. Chein's registered location was in Beverly Hills, California. [FOF 73, 93]. This action also violated the Controlled Substances Act.

While the record does not support a conclusion that these actions are directly attributable to the Respondent, the record also fails to contain evidence of the Respondent's taking action to correct these violations or to implement systems to ensure further violations of this nature would be prevented. In this light, I find that the Respondent's lack of action supports a revocation conclusion.

(e) *Import Issue*

Prior to importing a controlled substance, an entity needs to file an application for a registration with the DEA. Such applications are evaluated under the standards established in 21 U.S.C. section 958.[12] [FOF 184]. The Respondent is not registered to import controlled substances. [FOF 204].

The record contains an invoice indicating that the Respondent purchased controlled substances from a Mexican company. [FOF 203, 208]. From this invoice, the Government argues that the Respondent imported these controlled substances from Mexico without a DEA registration authorizing such conduct. The Respondent's importation is a violation of the Controlled Substances Act, the Government asserts. [FOF 183].

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[12] On March 2, 2004, the Respondent filed a request that I order the Government to produce sections 5211.4 through 5244.4 of the Diversion Investigators' Manual, because these sections regulate imports and exports. By this document, I hereby deny the Respondent's request. First, the Respondent has failed to cite to any authority that supports his assertion that I can order the Government to turn over documents the Government does not purport to rely upon in the presentation of its case against the Respondent. Further, contrary to the Respondent's assertion, the Diversion Investigators' Manual is not law binding upon this forum. In conclusion, I do not find that "due process" requires that the Government turn over internal manual pages to the Respondent in this matter. Accordingly, I deny the request.

However, the record contains conflicting evidence pertaining to this import issue. First, the record contains an invoice showing the purchase of controlled substances from Farmacia, a Mexican pharmacy. [FOF 208]. Yet the Government presented no direct evidence that the Respondent received a controlled substance that was shipped from Mexico to the Respondent in California.[13] [FOF 208].

Next, the record also contains evidence that the owner of the Mexican pharmacy, Dr. Romero, may have shipped the controlled substances from a location in San Diego, California. [FOF 204, 206]. Dr. Romero lived in Chula Vista, California. [FOF 205]. There are no shipping documents in the record to refute this evidence.

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[13] The Respondent filed several motions seeking documents he asserted were in the Government's possession that would establish the point of origin of the products purchased and shipped from Farmacia. However, the Government refused to turn over any documents to the Respondent related to this importation allegation other than the invoice, Government Exhibit 22. The Government asserted that the law enforcement privilege applied to the documents sought, and, therefore, the Government was unable to turn over the requested documents. Although I ordered the Government to provide me with copies of the relevant documents *in camera* so that I could determine the applicability of the law enforcement privilege to the documents, the Government refused to comply with my order. Thus, given the lack of evidence in the record concerning this importation, I conclude that the Government has not established this allegation by preponderating evidence.

After considering this evidence, I find that the Government has failed to prove, and the record fails to establish by a preponderance of the evidence, that the Respondent received imported controlled substances from Mexico. Therefore, I find that the Government has not established this violation of the Controlled Substances Act by preponderating evidence.

The Government also argues, in the alternative, that even if the Mexican controlled substances were actually shipped from Dr. Romero's California residence, by accepting this shipment, the Respondent violated the Controlled Substances Act because Dr. Romero was not registered to dispense controlled substances in the United States. Thus, the Respondent received controlled substances from an unregistered entity, in violation of the Controlled Substances Act. [Govt. Brief at 100, *citing to* 21 U.S.C. 822(e)]. I find this argument persuasive. It is a violation of the Controlled Substances Act for a registrant to purchase and receive controlled substances from an unregistered entity.

Thus, again, I find that the Government has proven by preponderating evidence that the Respondent's continued registration is against the public interest.

C. Export Application Issue

Pursuant to 21 U.S.C. Sections 958 and 823, the Deputy Administrator[14] may deny an application for a DEA Certificate of Registration as an exporter of controlled substances in Schedules III or IV if she determines that the granting of such registration would be "inconsistent with the public interest" as determined pursuant to 21 U.S.C. Section 823(d). Specifically, the Deputy Administrator should consider the following factors for this case:

> (1) Maintenance of effective controls against diversion of particular controlled substances and any controlled substances in Schedule III, IV, or V compounded there from into other than legitimate medical, scientific, or industrial channels;
>
> (2) Compliance with applicable State and local law;
>
> (3) Promotion of technical advances in the art of manufacturing these substances and the development of new substances;
>
> (4) Prior conviction record of applicant under Federal or State laws relating to the manufacture, distribution, or dispensing of such substances;

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[14] The Deputy Administrator has the authority to make such determinations pursuant to 28 C.F.R. §§ 0.100(b) and 0.104 (2003).

> (5) Past experience in the manufacture, distribution, and dispensing of controlled substances, and the existence in the establishment of effective controls against diversion; and
>
> (6) Such other factors as may be relevant to and consistent with the public health and safety.

Further, 21 U.S.C. Section 953 states in relevant part:

> (e) It shall be unlawful to export from the United States to any other country any nonnarcotic controlled substance in schedule III or IV or any – trolled substances in schedule V unless –
>
> > (1) there is furnished (before export) to the Attorney General documentary proof that importation is not contrary to the laws or regulations of the country of destination for consumption for medical, scientific, or other legitimate purposes;
> >
> > (2) it is exported pursuant to such notification or declaration, or in the case of any nonnarcotic controlled substance in schedule III, such export permit, notification, or declaration as the Attorney General may by regulation prescribe;

See also 21 C.F.R. § 1312.27.

1. Factor One: Maintenance of effective controls against diversion

As in the analysis above, the Respondent does not have adequate controls against diversion in the manner in which he stores his controlled substances. [FOF 18]. Specifically, all controlled substances received at PSLEI, regardless of who ordered the substances, are stored in a common area. Further, access to that area is not controlled. [FOF 18].

Another problem with the Respondent's handling procedures is his failure to conduct the required inventories. [FOFs 69, 78]. Without this accountability check, the Respondent would have no way of monitoring the receipt and distribution of his controlled substances. Therefore, analysis of this factor weighs in favor of denying the Respondent's application for an export registration.

2. Factors Two and Five: Compliance with applicable State and local law and past experience in the manufacture, distribution, and dispensing of controlled substances

Here, there is no dispute that the Respondent was shipping controlled substances overseas, either directly to patients, or to overseas doctors. [FOF 80, 86-87, 94, 193]. Further, there is no argument that the Respondent was not registered to export controlled substances, although his activities required such registration. 21 C.F.R. § 1301.13. [FOF 186].

Such conduct clearly violates the Controlled Substances Act.

In August of 2001, the Respondent was informed that it was a violation of the Controlled Substances Act for him to export controlled substances without a DEA registration authorizing such activities. [FOF 78]. However, the Respondent disagreed with DI DeSantis, arguing that he fell under an exception to this requirement. [FOF 79]. Although DI DeSantis explained that the exception was not applicable to the Respondent, he continued to export controlled substances without a DEA registration. [FOF 79, 81, 194]. Specifically, the record demonstrates that, between July 1, 2000 and February 5, 2001, there were 317 instances of the Respondent's exporting controlled substances. [FOF 191]. Such conduct fails to afford the DEA the opportunity to evaluate the proposed transactions to ensure that the U.S., as well as the country of destination, do not find that such exports violate their international treaties. [FOF 190].

I note that the record indicates that DI DeSantis may have incorrectly informed the Respondent that he needed export permits from the DEA before he could export any non-narcotic controlled substances to doctors overseas. [FOF 80]. However, DI Michaels correctly stated the procedure for an individual or entity to obtain approval to export non-narcotic controlled substances. [FOF 190].

Even if DI DeSantis provided the Respondent with erroneous information, her action does not alter the Respondent's responsibility to comply with the law. He should have ceased exporting controlled substances until this matter was resolved, rather than continue to disobey the law after being informed of the registration requirement. [See FOF 183-186].

The Deputy Administrator could also consider that the Respondent did file two applications for an export registration with the DEA. [FOF 199-200]. He obviously attempted to obtain the requisite registration. Yet, his continued exporting of controlled substances without a DEA export registration outweighs the benefits derived from the Respondent's attempts to obtain a registration. Given the political implications involved in the exporting of controlled substances and international treaties that need to be considered, the Respondent's conduct could have had a considerable impact upon the public interest in the receiving countries, as well as an impact upon our continued relationship with those countries. Such an impact is relevant in the Deputy Administrator's analysis of this case.

Therefore, I conclude that the Respondent's blatant disregard for the DEA's registration requirements prior to exporting controlled substances weighs in favor of denying his application.

3. Factor Three: Promotion of technical advances

The Respondent clearly developed an innovative treatment regime, for he actually patented his treatment process. [FOF 41, 45]. As part of his treatment, the Respondent dispenses controlled substances to his patients overseas. Therefore, his ability to export controlled substances would enhance his continued ability to develop hormone replacement therapy for his patients. Thus, I find that this factor weighs in favor of the Respondent's being granted an export registration.

4. Factor Four: Prior Conviction Record

The record contains no evidence of a prior conviction of the Respondent related to his handling of controlled substances.

5. Factor Five: Compliance with applicable State and local law and past experience in the manufacture, distribution, and dispensing of controlled substances

Given the above analysis, I find that the Respondent's past experience handling controlled substances weighs against his registration as an exporter of controlled substances.

6. Factor Six: Other Factors

The Respondent's willingness to engage in deception in his packaging of the controlled substances he is sending overseas also weighs against the Respondent's being granted an export registration. [FOF 192].

The Respondent also seems to argue that his export registration application was mishandled by the DEA, and that that somehow mitigates the Respondent's blatant disregard for the law. The record clearly demonstrates that the Respondent applied for an export registration in April of 2001, and that this application was not processed by the DEA. [FOF 195, 198]. However, I do not find the Respondent's argument compelling. The DEA's actions did not provide a justification for the Respondent to knowingly violate the law by continuing to export controlled substances without the needed DEA registration. Other legal avenues where open to the Respondent in the event he believed the DEA was somehow treating him and his application improperly. Violating the law was not such an avenue, however.

In conclusion, I recommend that the Respondent's application for an export registration be denied. His demonstrated willingness to disobey the law in his handling of controlled substances weighs heavily against his being authorized to export controlled substances to foreign countries.

The Respondent chose not to testify in this case. Although the Government argues that I should draw an adverse inference from his silence, I choose not to do so, given the outstanding grand jury investigation at the time of this administrative hearing. However, the record does fail to provide the Respondent's personal justification for his conduct. Further, the DEA does not have the Respondent's reassurances that he will not violate the DEA's regulation requirements in the future. Further, the record is silent regarding any remedial actions the Respondent may have taken to remedy his recordkeeping inadequacies and his controlled substances storage problems.

I acknowledge that the public has an interest in the continued access to the Respondent's total hormone replacement therapy. The Deputy Administrator could certainly take this interest into account in determining whether or not to revoke the Respondent's DEA registration and, whether or not to deny the Respondent's application for a DEA registration to export controlled substances.

V. Recommended Decision

Consistent with my findings and discussion, however, I recommend that the Deputy Administrator revoke the Respondent's DEA Certificate of Registration and deny his application for an export registration.

/s/ Gail A. Randall
Gail A. Randall
Administrative Law Judge

CERTIFICATE OF SERVICE

This is to certify that the undersigned on July 28, 2005, caused a copy of the foregoing to be placed in the interoffice mail addressed to Brian Bayly, Esq., Office of Chief Counsel, Drug Enforcement Administration, Washington, DC 20537, and a copy to be mailed, first class postage prepaid, to Counsel for the Respondent, Philip W. Boesch, Jr., Esq., The Boesch Law Group, 330 Washington Boulevard, Suite 600, Marina Del Rey, California, 90292.

/s/ Carlene R. Thomas
Carlene R. Thomas
Secretary to
The Honorable Gail A. Randall

United States Court of Appeals
For The District of Columbia Circuit

No. 07-1051 **September Term 2008**
DEA-72FR6580

Filed On: September 19, 2008

Edmund Chein, M.D.,

Petitioner

v.

Drug Enforcement Administration, et al.,

Respondents

BEFORE: Sentelle, Chief Judge, and Ginsburg, Henderson, Randolph, Rogers, Tatel, Garland, Brown, Griffith, and Kavanaugh, Circuit Judges

ORDER

Upon consideration of petitioner's petition for rehearing en banc, and the absence of a request by any member of the court for a vote, it is

ORDERED that the petition be denied.

Per Curiam

FOR THE COURT:
Mark J. Langer, Clerk
BY: /s/
Michael C. McGrail
Deputy Clerk

United States Court of Appeals
FOR THE DISTRICT OF COLUMBIA CIRCUIT

No. 07-1051 **September Term 2008**

DEA-72FR6580

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Edmund Chein, M.D.,

Petitioner

v.

Drug Enforcement Administration, et al.,

Respondents

BEFORE: Sentelle, Chief Judge, and Henderson and Randolph, Circuit Judges

ORDER

Upon consideration of petitioner's petition for panel rehearing filed on August 26, 2008, it is

ORDERED that the petition be denied.

Per Curiam

FOR THE COURT:
Mark J. Langer, Clerk

BY: /s/
Michael C. McGrail
Deputy Clerk

U. S. Department of Justice / Drug Enforcement Administration

CONTROLLED SUBSTANCES IMPORT / EXPORT DECLARATION

(Read Instructions on reverse before completing)

OMB APPROVAL
No. 1117 - 0009

See reverse for Privacy Act

CHECK ONE

☐ IMPORT DECLARATION — Nonnarcotic Substances in Schedules III, IV, V

☐ EXPORT DECLARATION — Nonnarcotic Substances in Schedules III, and IV and all substances in Schedule V

U.S. CUSTOMS CERTIFICATION

Date of Departure / Arrival

Name of Carrier / Vessel

Date of Certification

Signature of Customs Official

IMPORTER/EXPORTER (Name and Address)

DEA REGISTRATION NO.

BROKER OR FORWARDING AGENT, IF USED (Name and Address)

2. CONTROLLED SUBSTANCES TO BE IMPORTED OR EXPORTED

2a. NAME AND QUANTITY OF DRUG or PREPARATION *(Enter names as shown on labels; numbers and sizes of packages; strength of tablets, capsules, etc., CSA Drug Code and NDC Number)*	2b. CONTROLLED SUBSTANCE CONTENT OF DRUG OR PREPARATION expressed as acid, base or alkaloid. *(Enter names of controlled substances contained in the drug; compound, or preparation)*	2c. DATE IMPORTED/EXPORTED AND ACTUAL QUANTITY *(Completed by registrant at time of transaction)*

3. ☐ FOREIGN ☐ DOMESTIC PORT OF EXPORTATION (last U.S. Customs Port) AND APPROX. DEPARTURE DATE

☐ FOREIGN ☐ DOMESTIC PORT OF IMPORTATION (first U.S. Customs Port) AND APPROX. ARRIVAL DATE

4. MODE OF TRANSPORT; NAME OF VESSEL / CARRIER (if known)

NAME OF ALL INTERMEDIATE CARRIERS

5. NAME AND ADDRESS OF FOREIGN CONSIGNEE/CONSIGNOR

I hereby certify that the above named substance(s) to be ☐ Imported, ☐ Exported, are intended for ☐ Legitimate medical need, ☐ Scientific research, ☐ Other (If intended for reexport beyond the country of destination described in block 5 above, attach documentation per Title 21, CFR 1312.27.)

If used as "Export Declaration", attach documentation that importation is not contrary to the laws or regulations of the country of destination.

SIGNATURE OF AUTHORIZED INDIVIDUAL OF IMPORTER/EXPORTER, BROKER OR FORWARDING AGENT

DATE

NAME OF FIRM AND TELEPHONE NUMBER

DEA Form - 236
(Apr. 1988)

Previous edition dated 4/80 is OBSOLETE.

COPY 1

INSTRUCTIONS FOR COMPLETING FORM DEA-236

This form is to be used in notifying DEA of all Imports or Exports as required by Title III, PL91-513, Sections 1002 and 1003, as amended, (Controlled Substances Import and Export Act, 21 U.S.C. 952 and 953). This form may be prepared and signed by the actual Importer or Exporter or by the Broker or Forwarding Agent used. The following instructions supplement the parts of the DEA-236 which are not completely self-explanatory.

Part 1. "IMPORTER" means the authorized DEA registrant who receives the controlled substance; "EXPORTER" means the authorized DEA registrant who ships the controlled substance.

Part 2. Typical entries might read:

Strength:	10 mg tablets
Size or Weight (Bulk):	1,000 tablets/bottle 100 kilo/drum
Quantity:	100 bottles, 2 drums

If needed, use additional forms and distribute in the prescribed manner after the required documents are attached to each copy.

Part 3. Self-explanatory.

Part 4. Insert name of vessel or airline and flight number, together with all intermediate carriers. Furnish all information concerning the transportation of the goods known at the time of preparing form DEA-236.

Part 5. Enter DEA registration number, if known, for "Import Declaration", or foreign registration number, if applicable, for "Export Declaration".

INSTRUCTIONS FOR DISTRUIBUTING [sic] FORM DEA-236

If this form is prepared as a **Controlled Substance Import Declaration**, distribute as follows:

Copies 1, 2, and 3 must be forwarded to the foreign shipper. These copies will accompany the shipment to certain points.

Upon receipt of **Copies 1, 2, and 3**, the foreign shipper will present **Copy 1** to the proper foreign government agency or authority, if required, as a prerequisite to export authorization. **Copy 1** shall then accompany the shipment to its final destination and shall be retained in the files of the importer for a period of at least two years.

Copy 2 shall be detached by the customs official at the foreign port.

Copy 3 shall be removed by an official of the United States Customs Service at the port of entry, certified and signed by the customs official (after noting any discrepancies), and forwarded to the Drug Enforcement

Administration, Office of Diversion Control, International Drug Unit (ODOI), Washington, D.C. 20537.

Copy 4 must be forwarded at least 15 days prior to importation to the Drug Enforcement Administration, Office of Diversion Control, International Drug Unit (ODOI), Washington, D.C. 20537.

Copy 5 must be retained by the importer until receipt of **Copy 1.**

If this form is prepared as a **Controlled Substance Export Declaration**, distribute as follows:

Copies 1, 2, and 3 shall accompany the shipment to certain points:

Copy 1 shall remain with the shipment to its final destination.

Copy 2 shall remain with the shipment, to be detached and retained by the customs official of the foreign port of importation.

Copy 3 shall be removed by an official of the United States Customs Service at the domestic port of exportation, certified and signed by the customs official (after noting any discrepancies), and forwarded to the Drug Enforcement Administration, Office of Diversion Control, International Drug Unit (ODOI), Washington, D.C. 20537.

Copy 4 shall be forwarded at least 15 days prior to exportation to the Drug Enforcement Administration, Office of Diversion Control, International Drug Unit (ODOI), Washington, D.C. 20537. In cases where the 15 day notice cannot be given, a special waiver may be requested from the Administration.

Copy 5 shall be retained by the exporter as part of his records for a period of at least two years.

PRIVACY ACT INFORMATION

AUTHORITY: Sections 1002 and 1003 of the Controlled Substances Act of 1970 (PL91-513), as amended (21 U.S.C. 952 and 953).

PURPOSE: To obtain information regarding the importation of nonnarcotic substances in Schedules III, IV, and V and the exportation of nonnarcotic substances in Schedules III and IV and all substances in Schedule V.

ROUTINE USES: The Controlled Substances Import/Export Declaration produces special reports as required for statistical and law enforcement purposes. Disclosure of information from this system are made to the following categories of users for the purposes stated.

A. Other Federal law enforcement and regulatory agencies for law enforcement purposes.

B. State and local law enforcement and regulatory agencies for law enforcement and regulatory purposes.

EFFECT: Failure to complete this form will preclude requested importation or exportation of the referenced controlled substances.

Under the Paperwork Reduction Act, a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. Public reporting burden for this collection of information is estimated to average 15 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the Drug Enforcement Administration, FOI and Records Management Section, Washington, D.C. 20537; and to the Office of Management and Budget, Paperwork Reduction Project No. 1117-0009, Washington, D.C. 20503.

[LOGO] U.S. Department of Justice
Drug Enforcement Administration
DIVERSION CONTROL PROGRAM

Quick Reference

Controlled Substances Import/Export Declaration

(DEA-236 as Import)

The declaration is a quintuplicate-copy from:

Copies 1, 2 and 3 are to be forwarded to the foreign shipper as follows:

> ***Copy 1*** will be submitted by the foreign shipper to the proper government authority in the foreign country if required for issuance of an export authorization. Copy 1 will then accompany the shipment to its destination and will be retained on file by the importer.
>
> ***Copy 2*** will be detached and retained by the appropriate customs official at the foreign port.
>
> ***Copy 3*** will be removed, certified and signed by an official of the United States Customs Service at the U.S. port of entry into the United States, noting any discrepancies. After signature, Copy 3 will be forwarded to the International Drug Unit of the Office of Diversion Control, DEA.

> Copy 4 must be furnished to DEA by the importer not later than 15 days prior to the proposed date of importation.
>
> Copy 5 must be retained by the importer until receipt of Copy 1. At that time, the following information should be entered in Item 2c: actual quantity imported and date received. After this information is entered, it is requested that a copy be made and forwarded to DEA.

In emergency or unusual situations, a waiver of the 15-day advance notice may be requested in writing by the importer.

Further information regarding import declarations may be found in Title 21, Code of Federal Regulations, Sections 1312.18-19.

Importer's Instructions for Completing the DEA-236 Form

Item 1a – Mark import declaration box.

Item 1b – Enter name/address of importer as shown on DEA registration certificate. Address must be that to which the substance will be shipped.

Also enter DEA registration number.

Note that shipments cannot be delivered to a post office box; a street address is required!

Item 1c – Enter name and address of broker or forwarding agent, if used.

Item 2a – Enter names as shown on labels; numbers and sizes of packages; strength of tablets, capsules, etc.; CSA Drug Code and NDC Number.

Item 2b – Enter name and controlled substance content (in grams of the drug, compound or preparation to be imported, as well as the anhydrous acid, base or alkaloid content (in grams), if applicable.

Item 2c – Enter the date received and actual quantity imported once the shipment has been received and forward a copy to DEA

Item 3a – Mark box next to "foreign" and enter the city and country of foreign port of exportation and approximate date of departure.

Item 3b – Mark box next to "domestic" and enter city and state of domestic port of importation (U.S. Customs port where shipment will clear) and approximate date of arrival.

Item 4 – Enter name of importing carrier or vessel if known, together with all intermediate carriers. If importing carrier or vessel unknown, indicate mode of transport (air, ship, truck).

Note that import of controlled substances by mail is prohibited!

Item 5 – Enter name and address of foreign exporter.

Item A – Mark appropriate boxes regarding importer's certification of export.

Item B – Enter signature of authorized individual of importer, broker or forwarding agent.

Item C – Enter date declaration prepared.

Item D – Enter name of firm. Also enter the telephone number of the person who actually completes the form in case there are any questions.

In The Matter Of:

Edmund Chein, M.D.

Hearing Volume 4
January 31, 2003

Miller Reporting Company
735 8th Street, SE
Washington, DC USA 20003
(202) 546-6666

Original File 0131CHEI.TXT, 246 Pages
Min-U-Script® File ID: 4173259856

Word Index included with this Min-U-Script®

* * *

[736] BEFORE THE

UNITED STATES DEPARTMENT OF JUSTICE

DRUG ENFORCEMENT ADMINISTRATION

In the Matter of:	:	Docket Nos. 02-9
	:	
EDMUND CHEIN, M.D.	:	02-43

VOLUME IV

United States District Court

3470 12th Street

Room 3

Riverside, California 92501

Friday, January 31, 2003

The above-entitled matter came on for hearing, pursuant to Notice, at 9:00 a.m.

BEFORE:

HONORABLE GAIL A. RANDALL

Administrative Law Judge

[737] APPEARANCES:

On behalf of the Government:

STEPHEN A. SOLA, ESQ.

Drug Enforcement Administration

United States Department of Justice

Office of Chief Counsel

Washington, D.C. 20537

(202) 307-8085

BRIAN BAYLY, ESQ.

Drug Enforcement Administration

600 Army Navy Drive

Arlington, Virginia 22202

On behalf of Respondent:

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(310) 578-7888

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[740] PROCEEDINGS

JUDGE RANDALL: This is the continuation of a formal hearing before the Department of Justice, United States Drug Enforcement Administration, in the consolidated matters of Edmund Chein, M.D., Docket Number 02-9 and 02-43.

The Administrative Law Judge presiding is Gail A. Randall.

Do counsel have anything they wish to place on the record before we continue with the witness? Mr. Sola?

MR. SOLA: Yes, your Honor. The Government has served Doctor Garber and Doctor Garber's wife with a copy of the subpoena, and I'd like to issue the – make available to the Court the return service. I'm not sure if that actually gets placed formally in the record or if it's just something –

JUDGE RANDALL: Not usually. Usually counsel keep it in the event that they need to do anything with it.

MR. SOLA: Okay.

* * *

[949] management meeting. He brought the subject up.

Q: He told you he did not have to comply with 953(a), didn't he?

A: No. He said that he had an exemption under 953.

Q: So now after the management conference and after you sent this out to him and have had a fair amount of time and legal procedure go on, you – you are of the understanding that 953(a) doesn't have anything to do with Doctor Chein, correct?

A: That's correct.

Q: So if you would have told Doctor Chein that 953(a) is something he ought to look very carefully at and he was violating, you would be wrong, correct?

A: That's correct.

Q: Now, did you at any time tell anyone, Doctor Garber or Doctor Chein or anyone at Palm Springs Life Extension Institute that they had to have an export permit or a permit as an exporter?

A: Yes. I told Doctor Garber that.

Q: Now – now that –

[950] **A:** I believe it –

Q: – you look at this –

A: – said that on the front of this sheet too. You don't have to possess any permits to export.

Q: And is it your understanding now as you sit here today with the benefit of hindsight, that Doctor Chein does not require an export permit for the purpose of Schedule III substances?

A: Yes, he does if he's an exporter. He – he requires an exporter's registration, and once he has a registration, the permits are filed with headquarters to – for every export you send out, you have to have a permit from headquarters on what you're exporting.

Q: Well, is a permit from headquarters on what you're exporting something different than an exporter's permit?

A: Yes. Well –

Q: And an exporter's permit is something required not for Schedule III for but Schedule – for other scheduled substances, is that right?

[951] **A:** An exporter's registration is required for anyone exporting any – well, in our case, controlled substances out of the Continental United States or its territories.

Q: Are you familiar with DEA Form 161 or DEA Form 357?

A: No. I'd have to see them, please. They're probably the permits, but –

MR. BOESCH: Well, your Honor, may I approach?

THE WITNESS: I don't know. I'd have to look at them.

JUDGE RANDALL: You may approach, counsel.

MR. BOESCH: Marked for identification as exhibit next in order, which would be 1070, the DEA quick reference from the Web site, import export form guide.

MR. SOLA: Your Honor, I'd just ask that this – I saw this document and it was just identified as RX 1070. Is this previously noticed as a document?

MR. BOESCH: No. It's impeachment. May I [952] request the witness be shown Exhibit 1070, please?

JUDGE RANDALL: Yes. Any objections?

MR. SOLA: No, your Honor.

JUDGE RANDALL: Very well. The document has been handed to the witness.

BY MR. BOESCH:

Q: On page two of the exhibit, it describes DEA Form 161 as an application for permit to export controlled substances. Do you see that?

A: Yes.

Q: Okay. And if you look at page one on the form, DEA Form 161 is not required for Schedule III non-narcotic substances, is it?

A: That's correct.

Q: So if you told someone at Palm Springs, whether it's Doctor Garber or Doctor Chein or anybody, that they had to have an application for a permit to export controlled substances, you were wrong, correct?

MR. SOLA: Objection. Your Honor, I object to that question as argumentative, but also that there's been no foundation raised what this

* * *

In The Matter Of:

Drug Enforcement Administration
In the Matter of: Edmund Chein, M.D.

Hearing Volume 7
February 5, 2003

Miller Reporting Company, Inc.
735 Eighth Street, S.E.
Washington, DC 20003
(202) 546-6666

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Word Index included with this Min-U-Script®

* * *

[1522] BEFORE THE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION

In the Matter of: : Docket Nos. 02-9
:
EDMUND CHEIN, M.D. : 02-43

VOLUME VII

United States District Court

3470 12th Street

Room 3

Riverside, California 92501

Tuesday, February 5, 2003

The above-entitled matter came on for hearing, pursuant to Recess, at 9:17 a.m.

BEFORE:

HONORABLE GAIL A. RANDALL

Administrative Law Judge

[1523] APPEARANCES:

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[1524] INDEX

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WITNESSES	RECROSS	DIRE
Doris DeSantis	–	–
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[1525] PROCEEDINGS

(9:17 a.m.)

JUDGE RANDALL: On the record. This is a continuation of the formal hearing before the Department of Justice, Untied States Drug Enforcement

Administration, in the consolidated matters of Edmund Chein, M.D., Docket Number 02-9 and 02-43. The administrative law judge presiding is Gail A. Randall.

Before we continue with the witnesses, do counsel have any matters they wish to place on the record?

Mr. Sola?

MR. SOLA: Your Honor, there are some documents that I want to move into evidence. Is this an appropriate time to do this?

JUDGE RANDALL: Just one moment. I'll let you do that before we continue on with the case. Any other matters you wish to place in the record at this time?

MR. SOLA: No, your Honor.

JUDGE RANDALL: Mr. Boesch, anything?

[1526] **MR. BOESCH:** No, your Honor.

JUDGE RANDALL: Very well. All right. Mr. Sola, this is a good time.

MR. SOLA: Your Honor, at this time, the Government moves into evidence the tape of the interview with Connie Chein that took place with DEA investigators. This tape was played during the proceedings, and a copy has been provided to Respondent's counsel.

JUDGE RANDALL: All right, Mr. Sola. Excellent. Can you tell me what you've numbered it, please.

MR. SOLA: It should be Government Exhibit – I believe it's 144, but it may be 145. So let me just check my list.

JUDGE RANDALL: Certainly.

MR. SOLA: I believe it's Government Exhibit 144.

(The item referred to was marked for identification as Government's Exhibit No. 144.)

JUDGE RANDALL: Very well.

* * *

[1803] investigator was wrong.

I would submit there's a reason why Ms. De Santis was wrong, and the reason is this. She had never had a case involving a physician with testosterone, applying only controlled substances Schedule III or below, never. Her work, and the primary work of the DEA, as the evidence shows, is narcotics diversion.

Yes, I don't minimize the importance of monitoring and controlling substances at Schedule V, IV, and III. It's all important. I'm not arguing that. I'm explaining, the evidence is explaining to the Court why it is that they get into this situation where, twice in the same investigation, the first time she shows up and then the first time she meets the target, she's wrong in applying the law, twice, admittedly, not even a little bit, a lot wrong, way off.

How does that happen? Well, I submit it happens because those standards are applicable to narcotics, and that's the primary experience not only of the DEA, but of the Riverside office that [1804] this diversion investigator works in, and they don't have any kind of regulatory enforcement activity, ever, against a doctor who is only, clearly only, doing Schedule III or below, even to the point where he makes certain there is no doubt about it.

You know, he follows the advice of Mr. Gilbert, tears up his triplicates, has absolutely no possibility that anybody can be doing that anywhere in his facility. So there is a reason why they're wrong, but that doesn't excuse it. I'm still looking for rectification. As Ms. De Santis indicated, when people are wrong, it is rectified. You know, "What we do is we rectify. We do it maybe by a telephone call or another management conference or something." But after being wrong on August 23rd, there's nothing except revocation. An OSC is the next step.

Now, in terms of the legal argument that is Diversion Investigator De Santis was wrong and Doctor Chein was wrong, and neither one of them was accurate in terms of what standards ought to apply, [1805] there are some points in the evidence that will come out about what standards should apply, and how readily ascertainable are they?

The first item in evidence that your Honor can look at is Exhibit 48, headquarters that's supposed to know. When he submits his application, even though he doesn't think he has to, when he submits his application, even before his management conference, before he's had word one with Investigator De Santis, what happens in headquarters?

Somebody writes on it, "Already has DEA number," and refunds his money, on May 25th, refunds his money through a credit-card transaction that – it's not like he gets a check back that he can look at and say, "Oh, what happened?" It's just run through a credit card company, and he's never notified, to the point where, months later, he's saying, "What happened?"

Well, your Honor the DEA is required by law, mandatory, required to register him. It's not a question of them having the ability to ignore his [1806] registration application. The statute, it says, "Shall register." "Shall" means mandatory. It says, "Shall, unless," and the evidence is going to show that that standard was ignored.

The evidence in terms of looking at the Exhibit 48, when you review the evidence, I think you will see the initials on there. We are going to be requesting subpoenas, when we go back, of the individual who wrote that, because the inference from that evidence, when you look at the evidence, I think it has to be clear that the evidence is going to show that somebody, even at headquarters, wasn't attuned to the appropriate standard. And if someone at headquarters doesn't get it, how can a registrant in the field?

The DEA web site, the evidence will show that they have a very few registered exports who run the gauntlet to get registered exports who run the gauntlet to get registered with that application process. You'll see the numbers. They have lots of licensed doctors, but they don't have experience in dealing with the insistence that there be multiple registrations. The DEA doesn't.

*   *   *

BEFORE THE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION

- x
In the Matter of: :
EDMUND CHEIN, M.D. :
- x

Drug Enforcement Administration
600 Army Navy Drive
Arlington, Virginia

Wednesday, September 10, 2003

The hearing in the above-entitled matter convened, pursuant to notice, at 9:39 a.m.

BEFORE:

HONORABLE GAIL A. RANDALL
Administrative Law Judge

* * *

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WITNESS	DIRECT	CROSS
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WITNESS	REDIRECT	RECROSS
Sean Mahoney		
By Mr. Bayly	2283	–
By Mr. Boesch	–	2294
Wayne Michaels		
By Mr. Bayly	2351, 2360	–
By Mr. Boesch	–	2356

* * *

[2337] Q Okay. Now –

A If he would have told me that I'm going to export a Schedule II product, I would have told him that he would have needed to submit a DEA Form 161, which is an application for an export permit.

Q Now, at any time prior to this conference call or during this conference call, did you explain to anyone the difference between 161 and 236?

A I don't recall explaining anything about an export permit, no.

Q Now, and no one asked you, to the best of your recollection?

A To the best of my recollection, no.

Q Now, in your – about how many registrants would you say, give or take, you deal with in a given month?

JUDGE RANDALL: Mr. Bayly?

MR. BAYLY: Objection. It doesn't cover the affidavit or the declaration submitted. So it's not within the scope,

JUDGE RANDALL: Overruled. I'll allow [2338] you to inquire to put the declaration in context.

THE WITNESS: Maybe one or two a month. It's very infrequent. My job doesn't – I don't have a tremendous amount of involvement with registrants on a daily basis. So I would estimate one or two, maybe three.

BY MR. BOESCH:

Q Did you have an understanding from this discussion with Ms. Winkler that this was a unique situation?

A That's my opinion. In the five years up until this time, I had never came in contact with a situation of a unique kind of medical treatment that wanted to be exported. Most, 99.9 percent, of the individuals that we deal with are businesses that are exporting commercial shipments of pharmaceuticals. This was a unique situation in which Dr. Garber had indicated that they had come up with a specific kind of treatment modality and that the conversation was that it was important to make sure that the countries of import would authorize entry of those – of that type of treatment [2339] modality, the phentermine and the steroids.

Q When you're referring to commercial shipments of pharmaceuticals, do you understand do you understand what the term "consignment" means?

A Well, you're going to have to explain to me in what context you mean that.

Q Well, as a – do you expect that lay people are to understand what these DEA forms, for example 236, mean?

A Well, let me tell you that in my experience as a field investigator, as a group supervisor, as a staff coordinator, that when we go out and do what we call a pre-registrant investigation, and I can only speak for my experience about how I ran my shop, and that was that we went out and we met with the applicant for the registration. We explained to them the regulations. We went over it. And in at least the New Orleans Field Division, we provided actual copies of applicable CFR cites for that particular business activity in which that applicant was applying for.

* * *